JBAIDS System Manual

Idaho Technology Inc.

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For JBAIDS information – **https://jbaids.idahotech.com**

We strongly encourage users to visit our Web site for answers to frequently asked questions, updated information and additional insights into operating the JBAIDS System.

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Contact Idaho Technology by e-mail in the following areas:
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Quick Guides for setting up the instrument can be found in Appendix C.

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ABBREVIATION OF TERMS

A.....amp (ampere)
BLAST.....basic local alignment search tool
CD-ROM.....compact disk read-only memory
COE.....Common Operating Environment
Cp.....crossing point
DNA.....deoxyribonucleic acid
dNTP.....deoxyribonucleotide triphosphate
FRET.....fluorescence resonance energy transfer
ITI.....Idaho Technology Inc.
IVD.....*in vitro* diagnostic
JBAIDS.....Joint Biological Agent Identification and Diagnostic System
LED.....light emitting diode
µL.....microliter
nm.....nanometer
OS.....operating system
PBS.....phosphate-buffered saline
PCR.....polymerase chain reaction
PPE.....personal protective equipment
PTFE.....polytetrafluoroethylene (Teflon)
RNA.....ribonucleic acid
SNP.....single nucleotide polymorphism
Taq.....*Thermus aquaticus*
Tm.....melting temperature
USB.....universal serial bus
UV.....ultraviolet
V.....volt
W.....watt

INSTRUMENT MANUAL SYMBOLS

The following symbols can be found throughout this manual. Use the definitions below as a guideline to their interpretation.

This symbol defines a potentially hot surface. Use caution when working near these areas to avoid bodily injury. Keep flammables and combustibles at a safe distance.

This symbol warns the user to operate the instrument according to the instructions provided in this manual. If used otherwise, a potentially hazardous situation could result.

This symbol highlights user tips to operate the instrument more efficiently.

This symbol defines a Biohazard danger. Use standard laboratory technique when handling pathogenic material.

This symbol indicates a protected ground terminal. Connect this terminal to ground before making any electrical connections.

CHAPTER 1:

TECHNICAL COMPONENTS OF THE JBAIDS INSTRUMENT

Description of the JBAIDS Program

The Joint Biological Agent Identification and Diagnostic System (JBAIDS) program was created to provide rapid positive identification and diagnostic confirmation of biological warfare agents and other pathogens of operational concern for the four branches of the U.S. Military: U.S. Army, U.S. Navy, U.S. Air Force, and U.S. Marine Corps.

The JBAIDS instrument was created as a reusable, portable, and modifiable system capable of simultaneous, reliable identification of multiple biological warfare agents and pathogens of operational concern and clinical significance. This instrument is configured to support reliable, quick, and specific identification of biological agents from various clinical specimens and environmental samples. It also enhances force protection by providing medical personnel and commanders an expedient means to reliably and quickly identify naturally occurring or intentional biological threats.

The JBAIDS instrument is a man-portable modified commercial-off-the-shelf system. The instrument operates in various environmental conditions and passes a 1-meter drop test.

System Description

The JBAIDS instrument detects and identifies various microbes associated with infectious disease and biological warfare agents. Specific test reagents and DNA sample purification kits that are produced by Idaho Technology are used in conjunction with this instrument for detection of organisms.

The JBAIDS instrument is a field-hardened air thermocycler capable of automatically analyzing samples for the presence of targeted DNA sequences. The instrument combines rapid thermocycling technology and a real-time fluorimeter to identify test samples. Thermocycling amplifies DNA while the fluorimeter enables real-time detection. It is a rapid, robust, sensitive, and specific method of pathogen detection. The JBAIDS instrument is capable of analyzing 32 samples (including controls) in less than 40 minutes.

The JBAIDS instrument and laptop.

The instrument's basic features in transportation position.

Power Cord Socket and Power Switch
Auxiliary Power Port
Serial Port Cable Connection
Serial Number and Instrument Label
Voltage Rating Label
Deck LED Indicator Light
Air Intake Fan
Heat Duct Assembly in Transportation Position
Reaction Chamber with Sample Carousel

The heat duct assembly with a loaded sample carousel.

The JBAIDS instrument, laptop computer, centrifuge, serial cable, and cords are securely sealed inside a waterproof, carbon fiber case.

The case easily fits inside a reinforced backpack making transport more convenient and safe.

LIFTING HAZARD: Improper lifting of the instrument could result in a strain injury. Lifts over 3 feet in height require two people.

Each instrument comes with a rugged laptop, pre-loaded with software for run and analysis of the JBAIDS. It has a sealed magnesium alloy case, shock-mounted hard drive, and is moisture and dust resistant.

A 1 GB USB flash drive is provided with the laptop for record storage.

Temperature Control of the Instrument

Temperature control of the cycle chamber is modulated by a temperature sensor in the cycling chamber. Ambient temperature air is driven into the instrument by the intake fan, causing positive pressure to force the air through the heating duct and into the carousel chamber. The air is heated at the end of the heating duct by a heat coil and dispersed into the chamber by the secondary vortex fan. Cooling is done in a similar manner by forcing unheated ambient temperature air into the chamber to cool the samples.

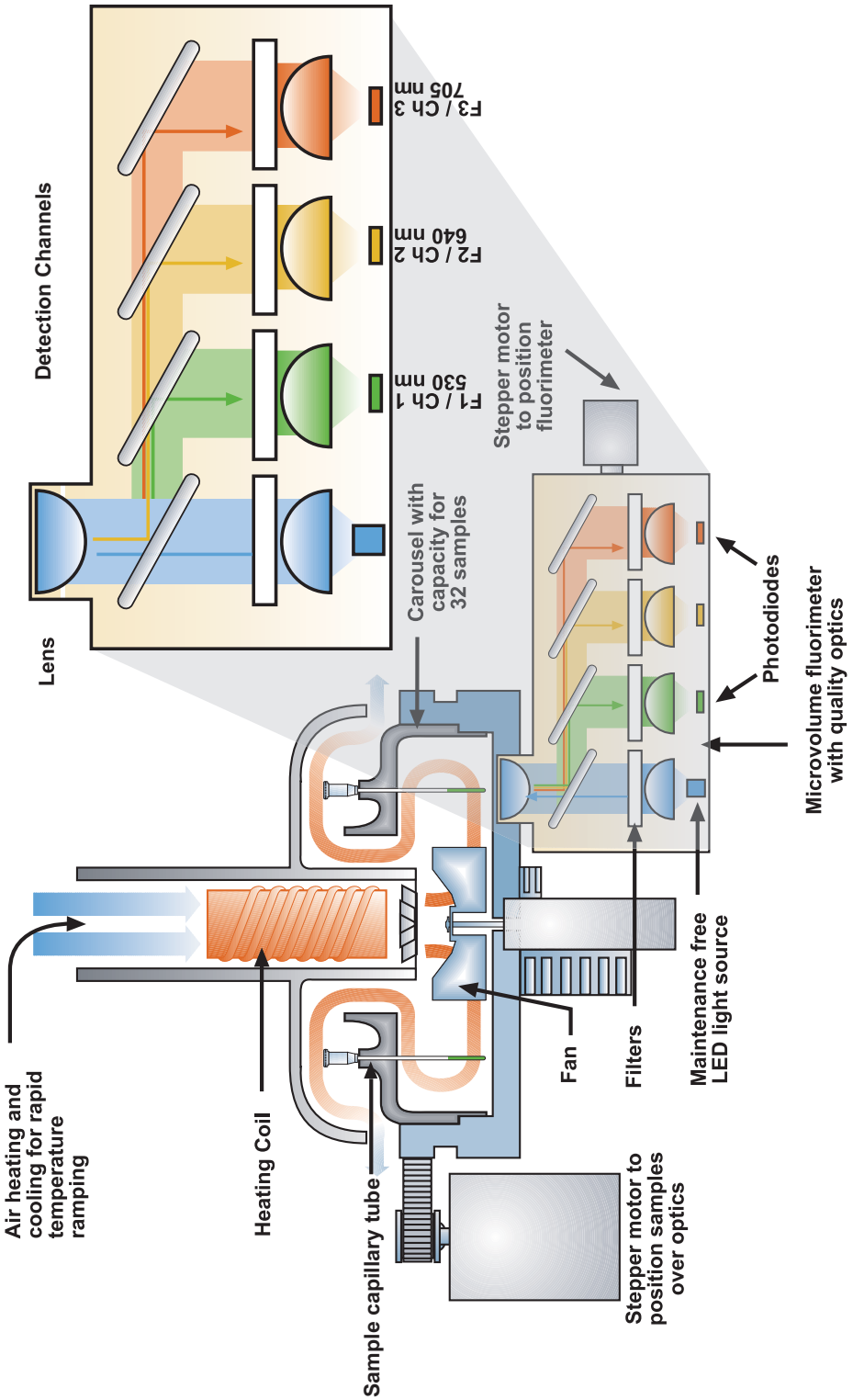
The over temperature sensor in the chamber prevents overheating if the temperature control sensor fails.

The Fluorimeter Component

A three-channel fluorimeter block is used for the real-time detection of the dyes/probes in each amplification reaction. The fluorimeter reads and stores data for each sample simultaneously in all three channels with every fluorescence acquisition. Excitation of each sample is from a light emitting diode (LED) that is filter tuned and passed through a dichroic mirror at 470 nanometers (nm). The three detection channels are filter tuned and correspond to 530 nm, 640 nm, and 705 nm respectively.

For fluorescence excitation, the instrument is equipped with an LED light source. This LED, which is an integral part of the fluorimeter, requires no maintenance and has an extremely long life span.

The fluorimeter provides three channels, which detect emitted light with varying wavelengths. Because of the high quality optics, the measurement is both extremely fast and sensitive. In a normal amplification run, measurement of a sample takes about 20 milliseconds.


Detection Channels
F3 / Ch 3
705 nm
F2 / Ch 2
640 nm
F1 / Ch 1
530 nm
Lens
Carousel with capacity for 32 samples
Stepper motor to position fluorimeter
Photodiodes
Microvolume fluorimeter with quality optics
Air heating and cooling for rapid temperature ramping
Heating Coil
Sample capillary tube
Fan
Filters
Maintenance free LED light source
Stepper motor to position samples over optics

Equipment Specification

Specifications for the JBAIDS Instrument

Durability Features

- Meets 810E US Military Transport Standard
- Carbon fiber outside case
- Resistant to temperature, humidity, shock and vibration. Air and water tight.
- Air, land, and sea transportable
- Withstands 1-meter drop test

Sample Description

- 32-sample capacity
- Composite glass/plastic reaction vessel loaded by centrifugation.
- 5–20 µL volume size

Fluorescence Acquisition

- Three-color optics modules: 530, 640, 705
- Excitation wavelengths from 450-490 nm.
- Acquisition modes: single, step, continuous

Temperature Control

- Range: Ambient temperature to 120°C
- Ramp Rate: 0.05–20 ºC/s

Power Supply

- 110/220 V auto-switching power supply unit.
- 220/110 V, 50/60 Hz, 7.0/6.0 A, 650 W [8 A, 230 V, 3AG fuse required]

Dimensions and Weight

- 10.5" (H) x 19.4" (W) x 14.3" (D)
- 35.75 lb including instrument, laptop computer, laptop bag, cords, and DVD drive. Weight does not include microcentrifuge, tool kit, backpack, and startup kit.

Specifications for the Laptop

Durability Features

- Designed using MIL-STD-810F test procedures
- Full magnesium alloy case with handle
- Moisture- and dust-resistant LCD, keyboard and touch pad
- Vibration and drop-shock resistant design
- Sealed port and connector covers
- Shock-mounted, removable hard drive in stainless steel case
- Rugged, dust-resistant hinges

CPU

- Low Voltage Intel® Pentium® M Processor 1.2 GHz
- 1 MB on-die L2 cache

Storage and Memory

- 40 GB Hard Drive
- 1.44 MB Floppy Disk Drive
- 256 MB SDRAM
- Combo DVD-ROM/CD-RW Drive

Wireless Local Area Network (LAN)

Intel® PRO/Wireless 2100 network connection 802.1 lb (disabled, see Chapter 3, *Installation and Setup*, "Installation of the Computer")

Display

- 13.3" 1024 x 768 (XGA) transmissive, anti-reflective TFT Active Matrix Color LCD
- Intel® 855GM graphic controller, UMA (Unified Memory Access) up to 64 MB
- External video support up to 1280 x 1024 at 16 million colors (24-bit color depth)

Power Supply

- Lithium Ion battery pack (11.1 V, 6.6 Ah)
- Battery charging time: approximately 3 hours/off, 5.5 hours/on
- Quick access battery/HDD cover for easy battery replacement
- Battery operation: up to 4 hours (with first battery), up to 10 hours (with second battery)
- AC Adapter: AC 100 V–240 V 50/60 Hz, Auto Sensing/Switching worldwide power supply
- Pop-up on-screen battery status reporting

Software

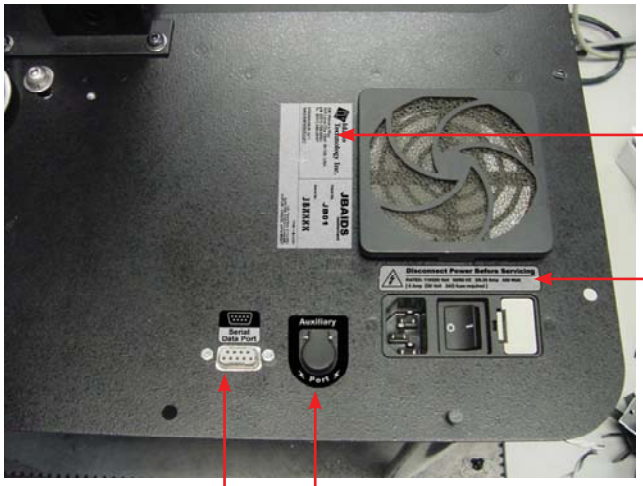
- Windows® 2000 Professional
- Setup, Diagnostics, DMI Viewer, On-line Reference Manual, Adobe® Acrobat® Reader, Panasonic® Battery Monitor

Dimensions and Weight

- 2.3"(H) x 11.8"(W) x 9.5"(D)
- 7.94 lb, including battery, FDD, and handle

Labeling

The following labeling is found on the JBAIDS instrument.



RIGHT

BACK

FRONT

LEFT

CHAPTER 2:

SAFETY PRECAUTIONS WHEN WORKING WITH THE JBAIDS INSTRUMENT

This symbol defines a potentially hot surface. Use caution when working near these areas to avoid bodily injury. Keep flammables and combustibles at a safe distance.

This symbol warns the user to operate the instrument according to the instructions provided in this manual. If used otherwise, a potentially hazardous situation could result.

This symbol highlights user tips to operate the instrument more efficiently.

This symbol defines a Biohazard danger. Use standard laboratory technique when handling pathogenic material.

This symbol indicates a protected ground terminal. Connect this terminal to ground before making any electrical connections.

LABORATORY USE

General Precautions

One of the most important rules of working in a laboratory environment is to avoid contamination. Some important rules to follow are:

- Do not return to a previous area without first ensuring proper decontamination procedures (i.e., washing and changing protective clothing and gloves).
- Use filter tips on pipettes when working with any liquid solution.
- Use different pipettes for setting up the reactions and for handling the samples.
- Follow the diagram when establishing a clean, contamination-free working environment.

Outside Sample Collection of Raw Sample
Lab Room Area 1 Sample Prep
Lab Room Area 2 Reaction Prep
Lab Room Area 3 Run Reaction
Start
Finish

Safety Precautions

Laboratory Procedures

- Avoid routine exposure to biohazards or potentially infectious material. Exposure can occur by inhalation, ingestion, or skin absorption.
- Potentially infectious material must be manipulated inside a biosafety laboratory.
- A biosafety cabinet must be used when potentially infectious material is used in procedures that may create aerosols or splashes. These activities include shaking, blending, and bead-beating.
- The centrifuge cap must be securely in place before starting the centrifuge.

Inhalation

- Minimize exposure by preventing splashes, sprays, or aerosols. Use a biosafety cabinet or other ventilation devices when possible.

Ingestion

- Never use mouth suction for pipetting or starting a siphon.
- Wash hands often.

Skin Absorption

- Wear personal protective equipment (PPE) when handling potentially infectious material.
- Use extreme caution when using sharp items.

Handling of Biohazard Wastes

- Use universal precautions whenever handling human-source bodily fluids or any sample/specimen that could possibly contain pathogens.
- Place all contaminated waste in a red or orange plastic bag labeled with the biohazard pictogram.
- Kill (i.e., autoclave or treat with 10% bleach [1 part bleach to 9 parts water]) all cultures, stocks, or live microorganisms before disposal.
- Place materials to be autoclaved in a proper autoclavable container in order to avoid spills and leaks inside the autoclave and the surrounding area.

Decontamination and Cleaning Procedures

The decontamination and cleaning procedures listed are intended to limit spread of DNA and/or polymerase chain reaction (PCR) amplicon or biohazards as a result of a broken capillary. Decontamination is necessary to prevent false-positive readings in subsequent assays. Only decontaminate areas of potential contamination. For instance, if a capillary breaks while in the JBAIDS reaction chamber, decontaminate the JBAIDS instrument, sample chamber, sample carousel, and bench top (or other area) surrounding the JBAIDS. If a capillary breaks while loading or unloading from the sample carousel, decontaminate only the sample carousel and any other potentially contaminated areas.

After a capillary breakage, change gloves and other potentially contaminated PPE. Change gloves often during decontamination process, especially during the first steps of decontamination and before touching any clean surface. All personal protective equipment should be disposed of after decontamination.

Materials

This list provides items that are necessary in a laboratory to keep contamination to a minimum.

- 10% bleach solution in a squeeze or spray bottle (1 part bleach to 9 parts water)
- Distilled water in a squeeze or spray bottle
- DNA*Zap*™, or equivalent DNA degrading system
- Paper towels
- Nylon brush
- Bleach wipes
- Lens cleaner
- Lens paper

Assessment of Risk Related to Capillary Breakage

Warning: It is **EXTREMELY IMPORTANT** that contamination from broken capillaries be contained and cleaned **IMMEDIATELY**. Capillaries that break after PCR can contain large quantities of target amplicon. This material, although noninfectious, is easily disseminated by normal human activity. Consequently, very small (molecular) quantities can be amplified by PCR in future runs, which will then be identified as positive by the JBAIDS instrument. Treat all broken capillaries as capable of contaminating your area.

If a capillary tube breaks in the sample carousel, take the following precautions to avoid contamination.

- Put on PPE such as gloves and safety shield.
- Stop the run and unplug the instrument before beginning cleanup.
- Ensure no one else uses any potentially contaminated areas or instruments.
- Decontaminate and dispose of the broken capillary using the following steps:
  - Dispose of potentially contaminated gloves and put on clean gloves.
  - Dispose of the potentially contaminated lab coat and put on a clean lab coat.
  - Clean up broken capillary, discard in capillary containment bin or biohazard sharps waste, and completely remove capillaries from carousel, if necessary.
  - Change gloves.
  - Follow decontamination procedures for cleaning affected areas.

WARNING: If the broken capillary contained human source material and/ or sample from a suspected pathogenic source, the risk of biohazard contamination exists in addition to the DNA amplicon contamination.

Sample Carousel Decontamination

Instrument carousels are interchangeable and disposable. Contact Idaho Technology to obtain replacement carousels. **Idaho Technology recommends replacement of contaminated carousels to minimize the possible spread of contamination. Also, the decontamination process can make insertion and removal of capillaries in the carousel more difficult, leading to capillary breakage and future contamination of the instrument.** Therefore, to allow continued use of the instrument after a broken capillary incident, always maintain at least one spare carousel with the instrument.

If a spare carousel is not available, the following procedure can be used to decontaminate the carrousel. Obtain a replacement carousel if the decontamination processes fail to eliminate all contamination or if the carousel is damaged.

1. Place carousel on bench top.
2. Spray 10% bleach (1 part bleach to 9 parts water) solution on both sides (top and bottom) of carousel and bench area. Let sit for 10 minutes.
3. Wipe carousel and bench area with paper towel.
4. Repeat step 2 and 3 twice, for a total of three wipes.
5. Spray distilled water on both sides of carousel. In particular, squirt distilled water into the capillary holes to remove any excess bleach.
6. Wipe carousel and bench area; dry with a new paper towel.
7. Spray both sides of carousel with DNA*Zap*, or equivalent product. See product for proper usage.

8. Rinse by spraying distilled water on both sides of carousel.
9. Wipe carousel and bench area dry with a new paper towel. Tap the carousel on your hand or clean bench top to remove excess distilled water.
10. Use a new nylon brush to dry out all holes in the carousel. Make sure carousel is dry, as residual bleach could alter fluorescence readings. If desired, check all carousel holes by inserting a clean, empty capillary. If insertion and removal of a capillary is difficult for any hole, repeat rinsing and drying steps.
11. Discard nylon brush.

Sample Chamber Decontamination

Warning: Be careful not to touch or bump the temperature sensors located in the sample chamber. Do not wipe bleach on the optics.

1. Remove carousel from instrument and decontaminate carousel by following the procedures above.
2. Remove the chamber fan by lifting it straight up to remove glass underneath the fan blades. Decontaminate chamber fan following procedures in "Sample Carousel Decontamination."
3. Remove glass from instrument (including the sample chamber) with a paper towel lightly moistened with distilled water. You may carefully remove glass from the optics with a moistened paper towel by touching the wet towel to the glass and then disposing of glass and towel. Be careful not to scratch the optics.
4. Wet a paper towel with 10% bleach (1 part bleach to 9 parts water) and wipe sample chamber and the inside of the heat duct assembly.
5. Repeat bleach step 4 twice with fresh paper towels for a total of three bleach wipes.
6. Wet a paper towel with distilled water and wipe carousel chamber and the inside of the heat duct assembly. **Do not wipe the optics.**
7. Repeat distilled water step 6 with a fresh paper towel.
8. Clean the optics of the instrument, if necessary, with lens cleaner and lens paper. Use light pressure when cleaning the optics.
9. Repeat optics cleaning step 8 with fresh lens paper.
10. Visually check the temperature control sensor to make sure it is straight and not bent to the side.

JBAIDS Instrument Decontamination

Note: If the sample carousel or chamber has been contaminated, follow the appropriate decontamination procedures listed before decontaminating the outside of the JBAIDS instrument.

1. Wet a paper towel with 10% bleach (1 part bleach to 9 parts water) solution and wipe entire instrument, including the bottom and bench top where the instrument had contact.
2. Repeat step 1 twice with fresh paper towels, for a total of three bleach wipes.
3. Change gloves, then wet a new paper towel with distilled water and wipe entire instrument, including the bottom and any place the instrument touched the bench top.
4. Repeat distilled water rinse once (step 3).

Decontamination of Bench Tops and Other Areas

1. Spray 10% bleach (1 part bleach to 9 parts water) solution on area of potential contamination. Let stand for 5 minutes.
2. Wipe with paper towel.
3. Repeat steps 1 and 2 twice, for a total of three wipes.
4. Spray area with distilled water.
5. Wipe dry with new paper towel.
6. Spray area with DNA*Zap*, or equivalent product. See product for proper usage.
7. Rinse by spraying area with distilled water and wiping dry.

CHAPTER 3:

INSTALLATION AND SETUP

This section describes how to set up and run the JBAIDS instrument. For replacement parts, see Appendix E for a list of items and their ITI national stock number (NSN) and part number (if available). Save the boxes and shipping material that accompany these items to ensure that they are packaged properly when being shipped to different locations.

Installation Requirements

Space and Power Requirements

- 32" x 16" space is needed for setup.
- Standard 110/220 volts AC grounded power source with surge protection is required for operation

Support Equipment Maximum Size and Power Requirements

A set of support equipment that is shipped on a pallet weighs approximately 1,700 lb and is 191 ft^3 and requires 22 amps of grounded power. When the entire JBAIDS instrument is set up with all of the accompanying support equipment, the footprint requires approximately 100 ft^2, or five 48" x 30" tables, plus walking room around the testing area.

Set-up Conditions

For operation, select a clean, well-ventilated area of sufficient size for both the instrument and the computer. This location should allow unrestricted airflow into the instrument's air intake.

Since the instrument releases hot air during operation, it is advisable to keep heat sensitive or highly flammable items at a safe distance from the instrument.

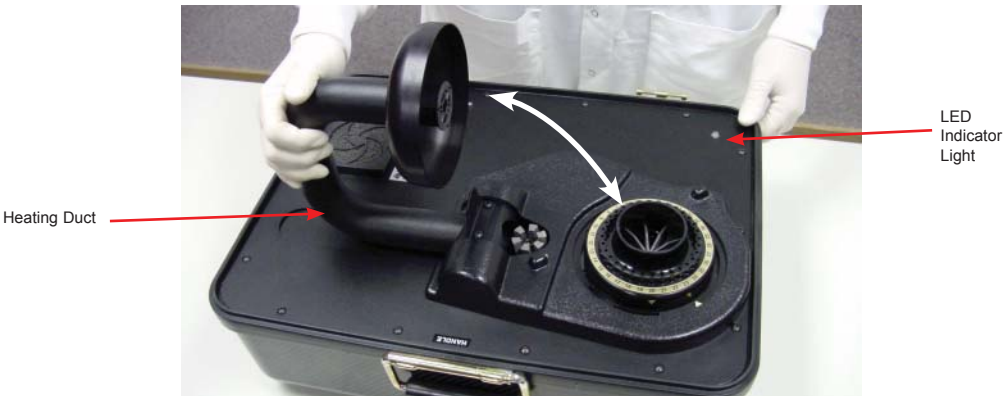
Installation of the JBAIDS Instrument

To unpack the instrument, set the backpack flat on its harness side.

1. Unsnap the four lock-straps and completely unzip the backpack. Open the backpack and remove the instrument.
2. Set the instrument on a sturdy flat surface and press the red pressure release button to equalize the pressure inside the instrument case.

3. Open the case by flipping up and turning the case latches counter-clockwise. Remove the top half of the case. The power and serial cables for the instrument are stored in a pouch in the top of the instrument case and should be removed for use.

4. Rotate the heating duct assembly to the operating position.



5. Follow the instructions for setting up the laptop computer before the instrument is turned on.

6. Plug the instrument power cord into the instrument and the opposite end of the power cord into a surge suppressed grounded power source. Flip the power switch on the top of the instrument to the **ON** position. Located on the deck is an LED indicator light which provides the status of the instrument.

Installation of the Computer

Use only the supplied serial cables when connecting the instrument to the laptop. Do not use cable extenders to increase the cable length.

WARNING: Ensure that the instrument is turned off before plugging in the serial cable.

1. Attach one end of the serial cable to the instrument serial port and the opposite end to the serial port in back of the laptop.

2. Plug the laptop power cord into the **AC Power In** on the right side of the laptop and connect the power cable from the laptop to a surge-suppressed grounded power source.
3. Open the laptop by pressing down and outward on the lid latch. Lift the screen up and position it for clear and easy viewing.

4. Slide the tab on the front right of the laptop to turn it on. The Windows Operating System (OS) will automatically load.

Note: All networking hardware has been disabled as part of the security profile. During startup, access to the hardware settings with the F2 key is disabled.

5. Log onto the laptop by entering a user name and password (provided by your lab supervisor or systems administrator).
6. Verify that the instrument power cord is plugged into the instrument and the opposite end of the power cord into a surge-suppressed grounded power source. Push the power switch on the instrument to the **ON** position. The LED indicator light will indicate the status of the instrument according to the following table.

Deck LED Indicator Light

	A red light indicates that the instrument is ready to run.
	A green light indicates that the instrument is running.
	A flashing green/red light indicates that an instrument error has been detected. (Note: It is normal for the LED to flash for 10 seconds when the instrument is turned on.)
	The absence of a light indicates that there is no power to the instrument.

Note: If the LED on the deck of the instrument continues blinking when the instrument is first powered on, then power off the instrument and let it sit for 5 seconds before turning it on again. If light continues to blink, refer to Chapter 6, *Maintenance and Troubleshooting*.

7. Upon initial setup of the JBAIDS laptop, a systems administrator should log in and set the correct date and time.
8. Once the instrument is turned on, and the indicator light is red, the instrument is ready to perform an analysis (see Chapter 4, *JBAIDS Software*).

Note: The laptop is equipped with universal serial bus (USB) ports that can be used for connecting printers, flash drives, and other USB devices. The software drivers for the printers, flash drives, etc. may not be installed on the computer. It is up to the individual user to install and maintain the drivers for the specific devices that may be used.

When removing a USB device, use the eject/remove hardware function located on the bottom right of your screen in the Task Bar. If this is not done, drivers for USB devices may not load correctly. If drivers do not load correctly, shut down and restart the computer. **Never start a computer with a flash drive connected to it.**

Installation of JBAIDS Software

Installation of the JBAIDS instrument software is not required. The PC comes pre-loaded with the necessary software to run, analyze, and report test samples. If there is a problem with the software or laptop computer, please contact ITI Technical Support.

Dismantling the JBAIDS Instrument

To dismantle the JBAIDS instrument, follow the setup instructions in reverse.

1. Power down the laptop and instrument then disconnect the power and serial cables.
2. Remove any capillaries that may be in the carousel and lock the carousel in place. The instrument should never be shipped with capillaries in the carousel.
3. Rotate the heating duct into the transportation position as shown below.

Auxiliary Power Port
Serial Port Cable Connection
Power Cord Socket and Power Switch
Deck LED Indicator Light
Heat Duct Assembly in Transportation Position
Reaction Chamber with Sample Carousel

4. Secure the laptop, cables, capillaries, and other items in the top half of the case.

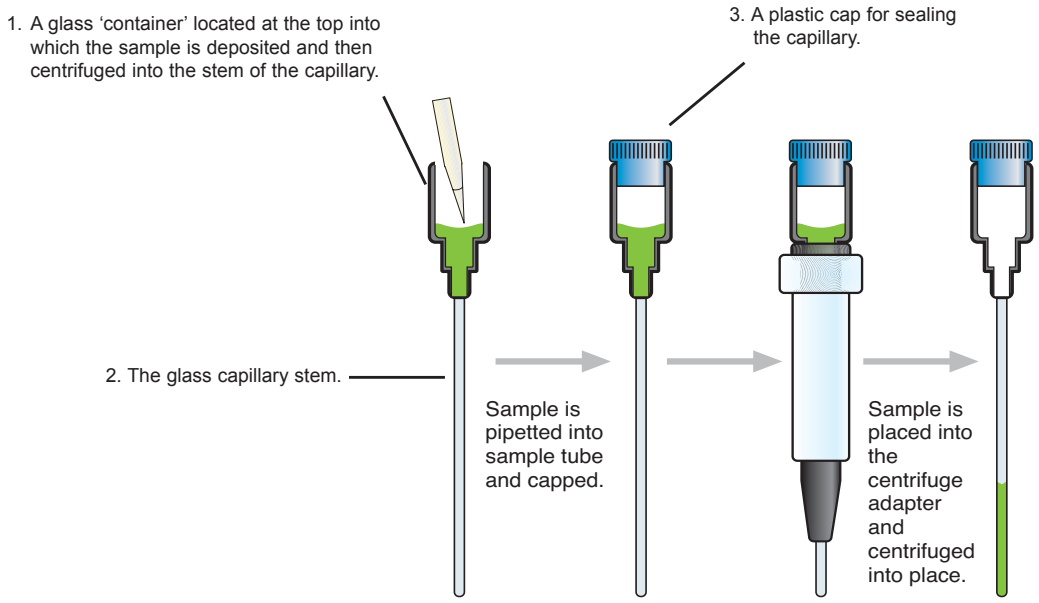
5. Lock the hinges of the case into position and secure the latches by turning them clockwise.

Sample Capillary Preparation and Loading

The sample capillaries provide the perfect reaction vessels for ultra rapid thermocycling applications because of their high surface-to-volume ratio. The capillaries have an outer diameter of 1.5 mm and a length of 3 cm and can hold sample volumes between 5–20 µL.

BROKEN GLASS HAZARD: Wear appropriate PPE when working with glass capillaries.

Capillary tubes consists of three parts:


1. A glass 'container' located at the top into which the sample is deposited and then centrifuged into the stem of the capillary.
3. A plastic cap for sealing the capillary.
2. The glass capillary stem.
Sample is pipetted into sample tube and capped.
Sample is placed into the centrifuge adapter and centrifuged into place.

For convenience, each capillary is individually numbered from 1–96 in each box.

Information on setting up reaction mixes and purifying the sample can be found in the product instructions that accompany the various kits.

BIOHAZARD WARNING: When working with the instrument, personnel may come in contact with biowarfare agents, clinical specimens, and medical laboratory chemicals. Wear appropriate PPE and use universal precautions when working with laboratory samples.

Loading Samples into the Capillary

1. Pipette 18–20 µL of sample into the top of the capillary. Cap the capillary and place it into the centrifuge with the adapters.
2. Centrifuge for about 3 seconds. This transfers the liquid down to the tip of the capillaries and prepares them for testing. Centrifuge adapters are included with the instrument for use in a standard centrifuge rotor with 1.5 mL sized microcentrifuge tubes.

Note: Ensure that the centrifuge adapters are placed in a balanced arrangement, and the lid is closed for safety precautions.

3. After centrifuging the samples, they are ready to load into the sample carousel.
4. When the reactions are completed, carefully remove any remaining capillaries to avoid breakage and carefully dispose of the capillaries into a disposable Sharps container.

Sample Carousel

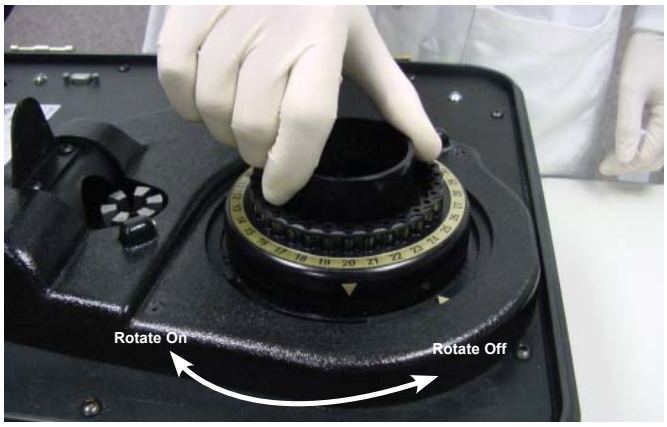
The instrument carousel is interchangeable from one instrument to another. Replacements are also available through ITI. If a sample capillary is broken in the carousel or the carousel otherwise becomes contaminated, it can be decontaminated by following the steps outlined in Chapter 2, *Safety Precautions When Working with the JBAIDS Instrument,* or discarded and replaced with a new one.

There are 32 sample slots in the sample carousel. Each slot is numbered to help the user identify and keep track of their samples. The numbers also correspond to the carousel positions that are assigned by the software.

Loading the Carousel

Before the samples can be loaded into the carousel, the test being performed must be selected in the software. Follow the steps in Chapter 4, *JBAIDS System Software* section of this manual to begin using the software.

BURN HAZARD: Since the instrument releases hot air (up to 92 °C) during operation, it is advisable to keep heat sensitive or highly flammable items at a safe distance.



1. Remove the carousel by turning it a quarter turn counter-clockwise to unlock it from the instrument. Lift the carousel straight up and out of the instrument to avoid breaking capillaries on the chamber fan.
2. Discard capillaries from previous run and replace the empty carousel by aligning the gold arrows on the outside of the carousel and the deck plate.
3. Lock the carousel into place by turning it a quarter turn clockwise.
4. Carefully place prepared capillaries into the carousel as directed in the diagram shown in the software wizard.
5. Position the heating duct assembly over the samples to perform a test.

CHAPTER 4:

JBAIDS SOFTWARE

Introduction

The JBAIDS software is designed for users of all skill levels from beginning operators to the more experienced advanced operators. It includes a step-by-step Wizard to allow users to quickly create, perform, and store tests as well as an advanced analysis mode that allows advanced operators to provide in-depth analysis of tests.

The software is presented in three sections:

- **Start Test**—This is the Wizard module that walks users through steps to quickly build, run, and save tests. Instructions on how to run the Wizard can be found in this chapter.
- **Analysis**—This mode allows advanced operators to edit analysis settings, create macros to run predetermined protocols, edit target names, view analyses belonging to all users, apply templates, and more. Instructions on how to perform these tasks can be found in this chapter.
- **Maintenance**—This mode allows advanced operators and operators to view critical information concerning the instrument. Instructions on how to perform maintenance tasks can be found in Chapter 6, *Maintenance and Troubleshooting.*

Software Access and Permissions

The software has four levels of access, each one with varying permissions. Each account has its own user login and password. View the comparison table to see the type of access and permissions given.

Task	Operators	Advanced Operators	Security Manager	System Administrator
Run an analysis using the Wizard	✔	✔		
Edit sample names	✔	✔		
Edit target names	✔	✔		
Edit sample and run notes	✔	✔		
Edit sample information	✔	✔		
Read/View analyses belonging to other operators; cannot modify or delete them	✔	✔		
Program a run		✔		
Edit analysis settings		✔		
Create macros (pre-defined test parameters)		✔		
Add an analysis module to a test		✔		
Apply templates and delete objects they own		✔		
All user management is handled through the COE programs. The Security Manager can create and unlock user accounts.			✔	
View/Modify/Delete instruments		✔		
Change the com port and the display name of instruments		✔		
Add printers and other hardware to the JBAIDS laptop				✔
Change time and date on the JBAIDS laptop				✔
Install software on the laptop, including JBAIDS software upgrades				✔

User Accounts—Common Operating Environment

The Common Operating Environment (COE) was developed by the U.S. Military to manage security for software created by Federal contractors. To use the JBAIDS software you must have a COE user account. User accounts have different levels of access to the software, depending on

- Whether the Government's COE kernel is installed.
- The *role* assigned to the user account

When you start the JBAIDS software, the software determines whether the COE kernel is installed. When installed, all user management is handled by the COE programs. The COE security manager assigns specific roles in the software when users are created. Logging in to the laptop logs you into COE, which controls your software access. Login to the JBAIDS software is not required.

Logging in to a Common Operating Environment System

Excerpt taken from the Common Operating Environment (COE) Security Features User's Guide (SFUG)

The JBAIDS software and laptop are compliant with the COE as outlined by the Department of Defense (DOD). All users must first login to a Windows NT system before being allowed access to any system resources.

1. To login, press **Ctrl+Alt+Delete**.
2. The DOD Login Warning Banner will appear.

> This is a DOD computer system. This computer system, including all related equipment, networks and network devices (specifically including Internet access), are provided only for authorized U.S. Government use. DOD computer systems may be monitored for all lawful purposes, including to ensure that their use is authorized, for management of the system, to facilitate protection against unauthorized access, and to verify security procedures, survivability and operational security. Monitoring includes active attacks by authorized DOD entities to test or verify the security of this system. During monitoring, information may be examined, recorded, copied and used for authorized purposes. All information, including personal information, placed on or sent over this system may be monitored. Use of this DOD computer system, authorized or unauthorized, constitutes consent to monitoring of this system. Unauthorized use may subject you to criminal prosecution. Evidence of unauthorized use collected during monitoring may be used for administrative, criminal or adverse action. Use of this system constitutes consent to monitoring for these purposes.

3. Log in to the login dialog box. The user enters his or her **username** and **password**. Entering an incorrect password three consecutive times will lock the user's account, preventing login. Only the security manager can unlock a user's account.

Note: Upon initial login to the system, the user is automatically required to change the password so that only the user knows the password. A box will appear requesting the old password and the new password. Entering the password information into this box will change the user's password.

Changing Passwords

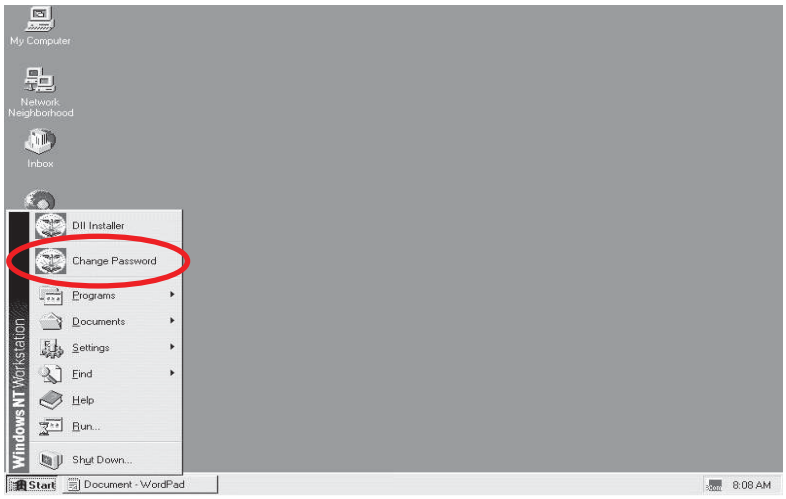
Note: Upon receiving the password expiration warning, ("Your password will expire in X days."), use the COE Change Password Tool to change your password BEFORE it expires. This provides the best means to keep passwords synchronized across the entire COE Administrative Domain and prevent users from being locked out of the JBAIDS laptop.

Follow these basic rules when assigning password on JBAIDS instrument computers:

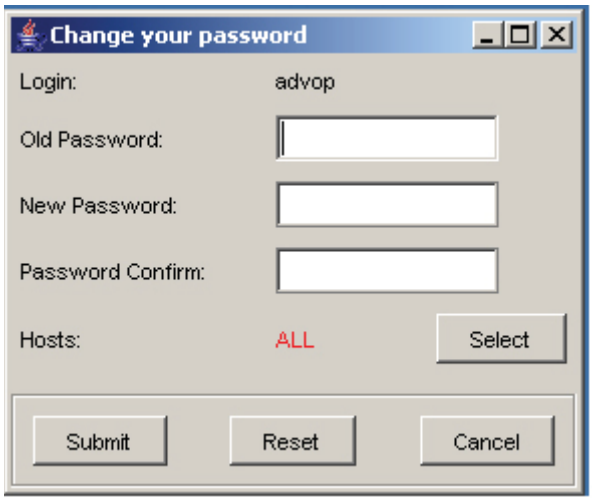
- Change your password every 30 days (COE requirement).
- Passwords cannot be changed more than once every 14 days.
- Passwords are case sensitive.

- Passwords must contain at least one capital letter and one number.
- At least two characters need to be distinct from the last 24 passwords.
- All passwords need to have greater than 8 characters.

1. Click on the **Start Menu** button at the bottom left of the computer screen.
2. Click on the **Change Password** Tool.



3. When the **Change your password** dialog box appears, enter the old and new passwords.
4. Enter the new password in the Password Confirm field.



Note: It is strongly recommended that users change their passwords on ALL JBAIDS instrument computers at the same time. Password synchronization problems may occur if passwords are changed only on individual computers.

5. Use the default hosts (ALL) .
6. Select the **Submit** button at the bottom of the dialog box.
7. A Status Summary dialog box will confirm the password change.

Logging Off the Laptop

When leaving a computer for any length of time, users should either log off or lock the computer in order to protect the computer and the user's data from others who may take advantage of the open session.

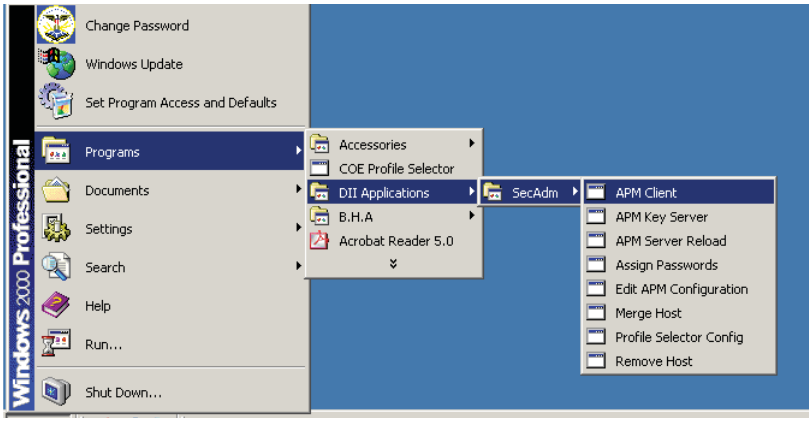
Logging off a computer allows other users with valid accounts to use the computer without disrupting the previous user's data, whereas locking the computer locks the interactive user interface but does not close the currently logged-in user's processes.

1. To log off the laptop, press **Ctrl+Alt+Delete** and then choose the **Log Off** button in the Windows Security dialog box. A pop-up dialog box will confirm that you wish to end your session; choose **OK** to continue the logoff.
2. To manually lock the computer, press **Ctrl+Alt+Delete** and then choose the **Lock Computer** button in the Windows Security dialog box. To unlock the computer, you must press **Ctrl+Alt+Delete** and enter your password.
3. The computer will automatically lock after 15 minutes of being idle and the **Computer Locked** dialog box will appear. To unlock the computer, you must press **Ctrl+Alt+Delete** and enter your password.

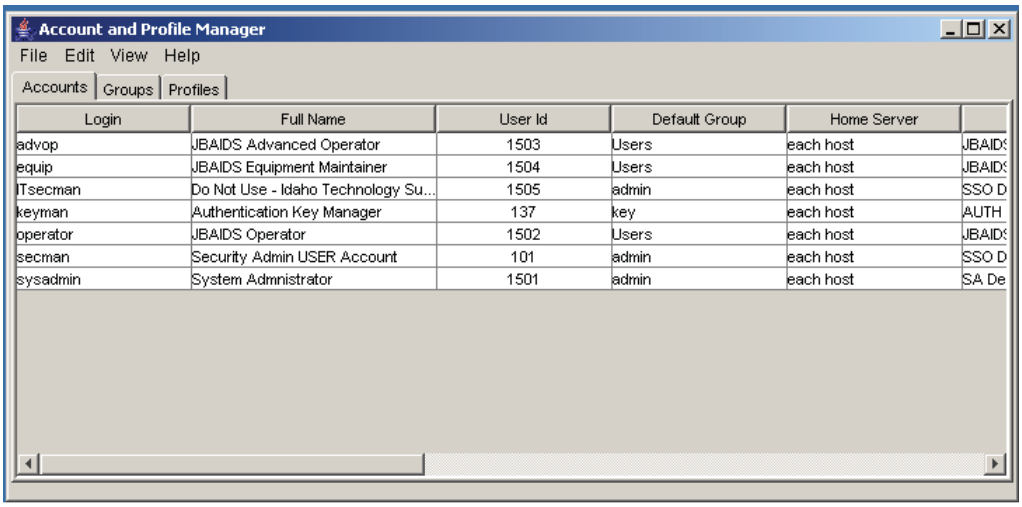
SECURITY MANAGER TASKS

Creating New Users

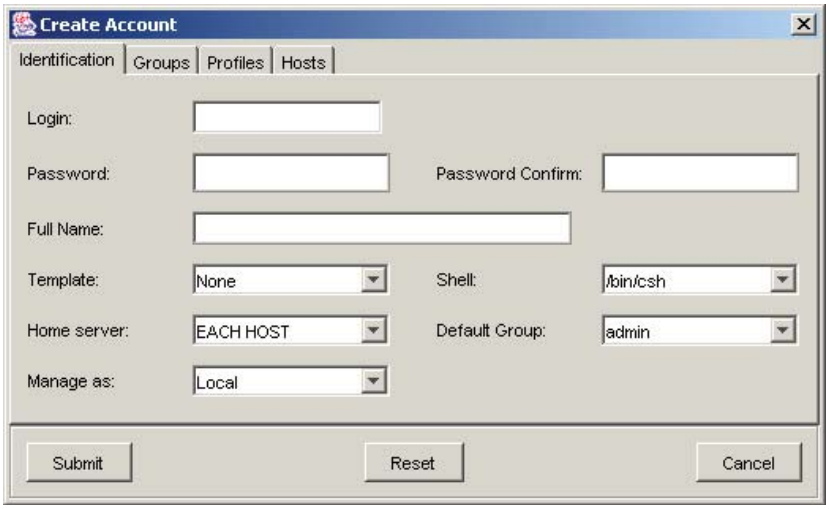
1. Log on to Windows as security manager using **secman** as the username and the current password.
2. From the **Start Menu** select **Programst/Dll Applications/SecAdm/APM Client**.



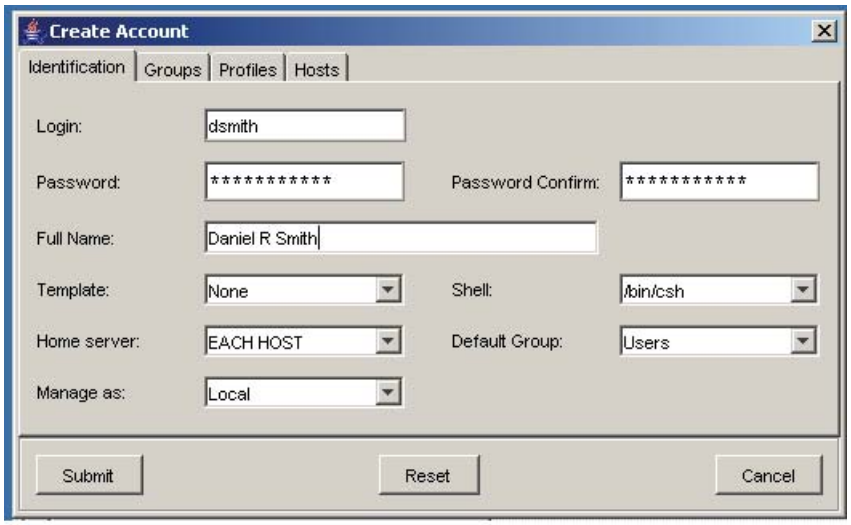
3. When prompted for the APM master authentication key enter "**apmauth**".
4. A dialog with the caption "Please wait" may display the status of several operations. Wait until this dialog has closed.
5. Select the **Accounts** tab on the **Account and Profile Manager** window.


Account and Profile Manager
File Edit View Help
Accounts Groups Profiles
Login Full Name User Id Default Group Home Server
advop JBAIDS Advanced Operator 1503 Users each host
equip JBAIDS Equipment Maintainer 1504 Users each host
ITsecman Do Not Use - Idaho Technology Su... 1505 admin each host
keyman Authentication Key Manager 137 key each host
operator JBAIDS Operator 1502 Users each host
secman Security Admin USER Account 101 admin each host
sysadmin System Admnistrator 1501 admin each host

6. From the **File** menu select New Account.
7. On the **Create Account** window, select the **Identification** tab. Enter the user's login, a temporary password, and the user's Full Name. Users will be required to change their passwords the first time they login to the computer.
8. Follow these basic rules when assigning the user name on JBAIDS instrument computers.
   - The login will be the user name.
   - User name is not case sensitive.
   - User name must contain two to eight characters.
   - The Full Name will appear on JBAIDS reports and in the Navigator.
   - Suggested format for User name is the user's first initial and up to seven letters of the user's last name.

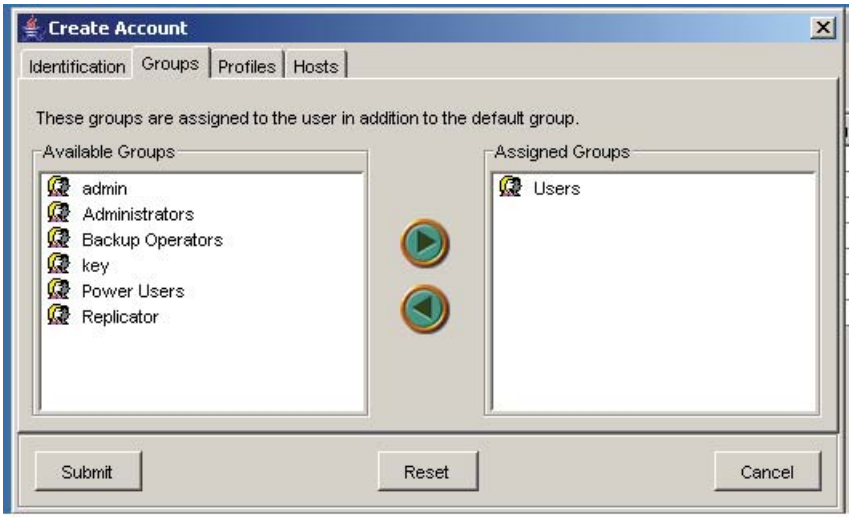


9. Change the **Default Group** to **Users** for operator and advanced operator accounts.

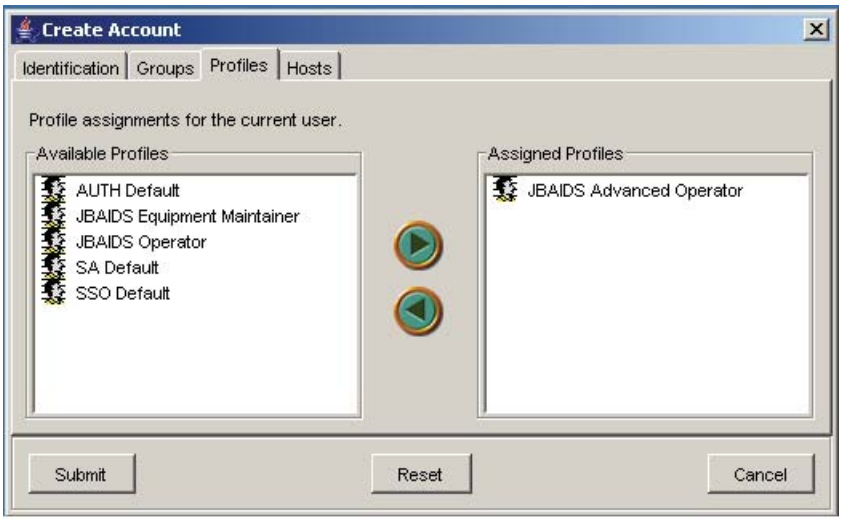


Note: The submit button should not be clicked until all four tabs on the Create Account window have been selected and the required information completed.

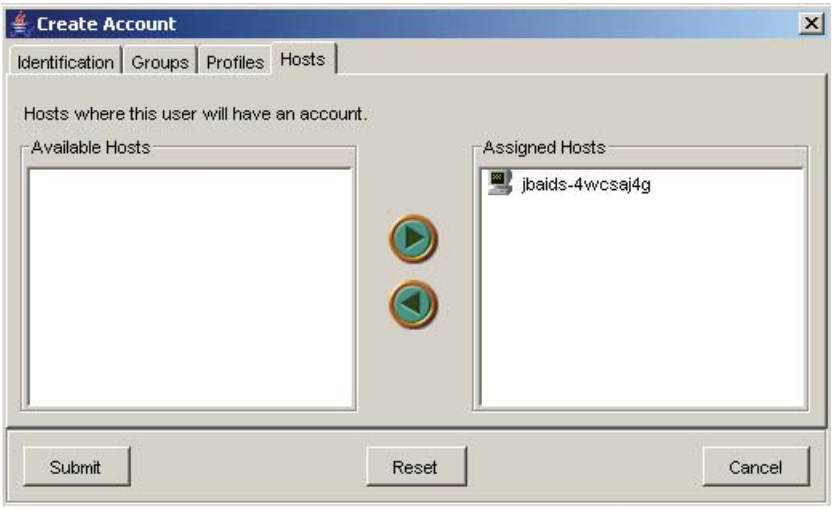
10. Select the **Groups** tab. From the Available Groups select Users and click on the right arrow between the Available Groups and Assigned Groups. The Users group will then be listed in the Assigned Groups.



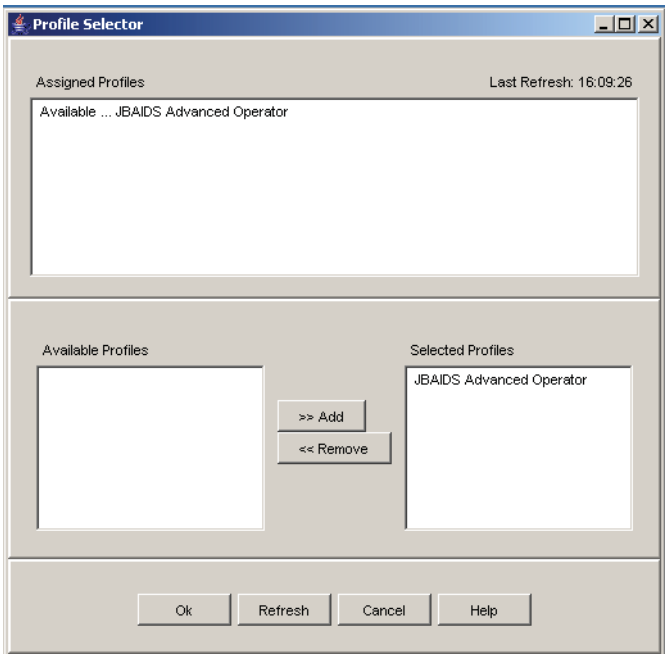
11. Select the **Profiles** tab. Select the JBAIDS Advanced Operator or the JBAIDS Operator profile. The one selected depends on the rights the new user needs to have in the JBAIDS software. Click on the right arrow between the Available Profiles and the Assigned Profiles. The selected profile will be listed in the Assigned Profiles.



12. Select the **Hosts** tab. There should be a single host listed in the Available Hosts. Select this host and press the right arrow between the Available Hosts and Assigned Hosts lists. The host will now be listed in the Assigned Hosts.



13. Click on the **Submit** button to create the new account. A dialog with the caption “Please wait” will display the status as the user is created. Click **Okay** on the Status Summary window.
14. Log off as security manager and log on as a new user.
15. When the user logs on the first time to their new account they will be prompted to change their password. Follow the steps in “Changing Password.”
16. When the newly created user logs on the first time, they will have to select their profile or the JBAIDS Program will not appear in the Start Menu/DII Applications menu pathway. To select a profile, click on the Windows 2000 **Start** button. Select **Programs/COE Profile Selector**. The Profile Selector will be displayed. There will be a single profile in the Available Profiles list. Double click that profile to move it to the Selected Profiles list. Press the **OK** button. A dialog saying “Starting/Stopping session/session_exit process” will be displayed. Wait until the dialog has closed to continue. When the success dialog is shown, press **Done** to close.



Profile Selection

When a user has been authenticated and has established a session, he or she will see a familiar desktop with applications and settings that are the same as the last time he or she logged on. This collection of assigned applications and settings is called a profile. Windows NT will assign one of two User Profiles to each valid user, either Local and Roaming. The JBAIDS COE computers cannot be connected to a network so Roaming Profiles are not available to JBAIDS users.

Local

Local profiles are specific to the local instrument on which they are created. One computer can store multiple profiles for multiple users who log in to that computer. A local profile is user and computer specific. It is created when a user first logs in at a Windows NT computer and is used when a user does not have a roaming profile.

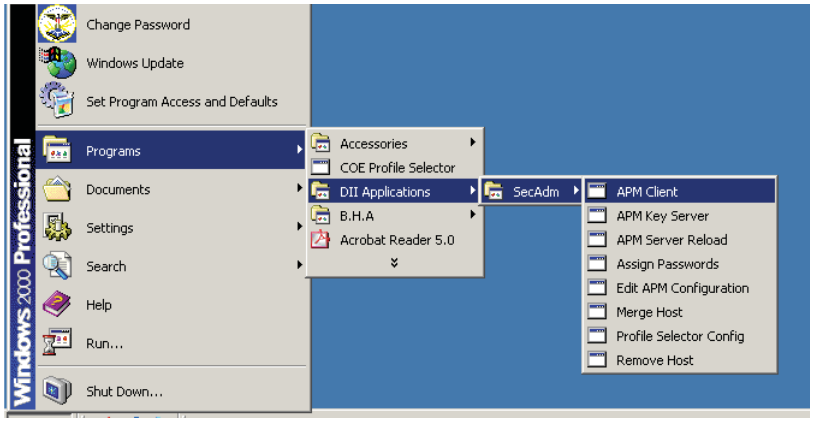
Unlocking a User Account

There are two ways that users can lock their accounts. The first is during initial login, where the user types the wrong password three times causing the system to lock. The security manager will be required to unlock the computer in this situation. However, users must wait 15 minutes before trying a new password.

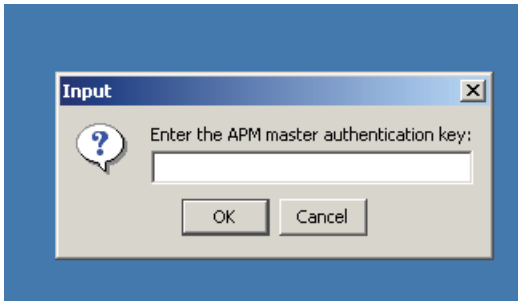
The second lockout situation occurs when the user leaves the instrument on for awhile, which triggers the screen saver to come on, then comes back and tries to log on to the screen saver. In this situation, if the user leaves the computer alone for 15 minutes, the computer will reset, and they can reenter the password.

For the first type of lockout situation, the security manager should use the following steps to unlock the computer.

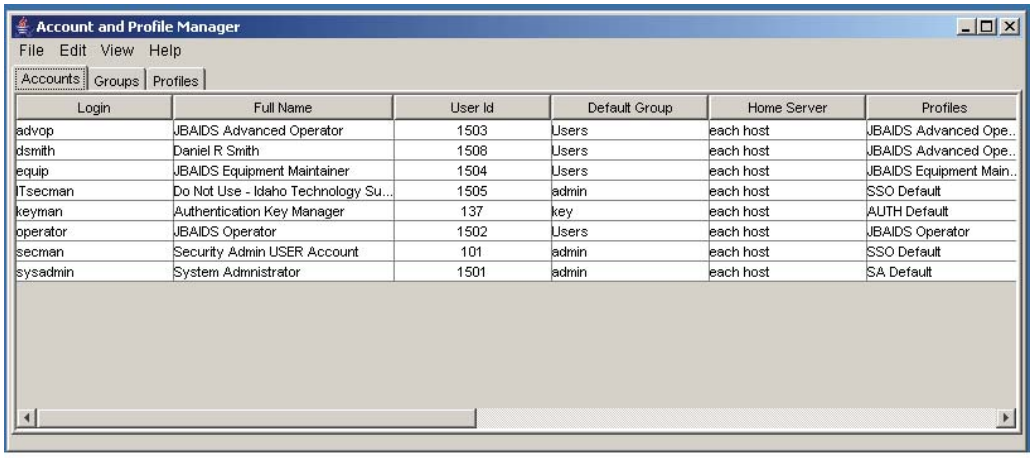
1. Login as Security Manager.
2. From the **Start Menu** select **Programs/DII Applications/SecAdm/APM Client**.



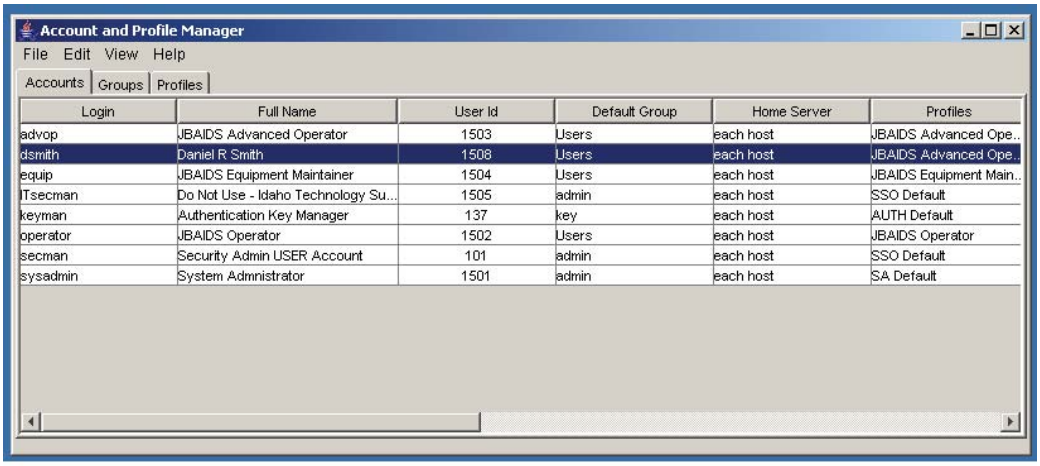
3. When prompted for the APM master authentication key enter **apmauth**.



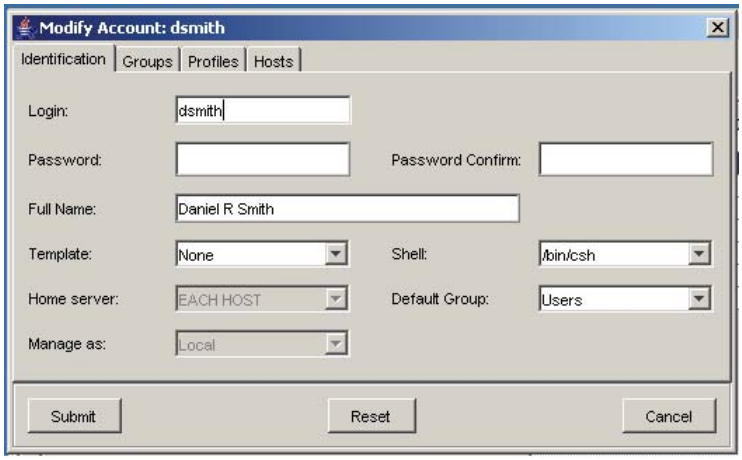
4. A dialog with the caption “Please wait” may display the status of several operations. Wait until this dialog has closed.
5. Select the **Accounts** tab on the **Account and Profile Manager** window.


Account and Profile Manager
File Edit View Help
Accounts Groups Profiles
Login | Full Name | User Id | Default Group | Home Server | Profiles
advop | JBAIDS Advanced Operator | 1503 | Users | each host | JBAIDS Advanced Ope..
dsmith | Daniel R Smith | 1508 | Users | each host | JBAIDS Advanced Ope..
equip | JBAIDS Equipment Maintainer | 1504 | Users | each host | JBAIDS Equipment Main..
ITsecman | Do Not Use - Idaho Technology Su... | 1505 | admin | each host | SSO Default
keyman | Authentication Key Manager | 137 | key | each host | AUTH Default
operator | JBAIDS Operator | 1502 | Users | each host | JBAIDS Operator
secman | Security Admin USER Account | 101 | admin | each host | SSO Default
sysadmin | System Admnistrator | 1501 | admin | each host | SA Default

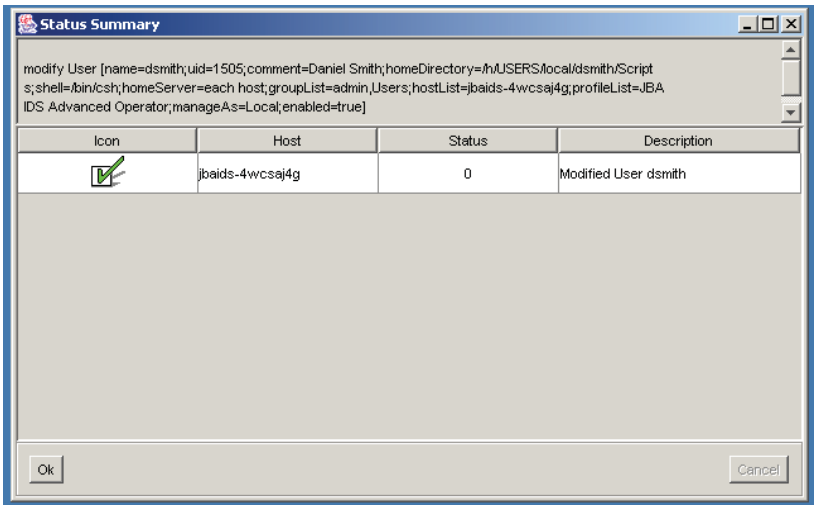
6. Select the user account to be unlocked.


Account and Profile Manager
File Edit View Help
Accounts Groups Profiles
Login Full Name User Id Default Group Home Server Profiles
advop JBAIDS Advanced Operator 1503 Users each host JBAIDS Advanced Ope..
dsmith Daniel R Smith 1508 Users each host JBAIDS Advanced Ope..
equip JBAIDS Equipment Maintainer 1504 Users each host JBAIDS Equipment Main..
ITsecman Do Not Use - Idaho Technology Su... 1505 admin each host SSO Default
keyman Authentication Key Manager 137 key each host AUTH Default
operator JBAIDS Operator 1502 Users each host JBAIDS Operator
secman Security Admin USER Account 101 admin each host SSO Default
sysadmin System Admnistrator 1501 admin each host SA Default

7. Select **Edit** from the menu, then select **Modify** from the drop down menu.



8. Enter a new password in the **Password** field. Reenter the password in the **Password Confirm** field.
9. Click on the **Submit** button. A dialog box with the caption “Please wait” will display the status as the user account is modified.
10. Click the **OK** button on the Status Summary window when the process is complete.



11. Exit from the Account and Profile Manager window.
12. Log off as the Security Manager.

Note: When the user logs on the next time they will be prompted to change their password.

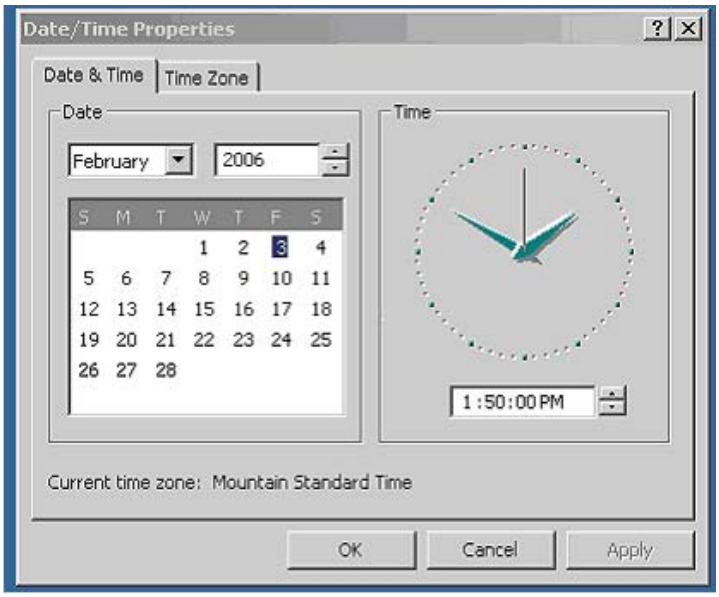
SYSTEM ADMINISTRATOR TASKS

Add Printers

1. Log on to Windows as system administrator using **sysadmin** as the username and the current password.
2. When the desktop screen comes up, place the printer driver CD in the CD/DVD drive in the JBAIDS computer.
3. Connect the printer to the power source and attach the printer cable to the JBAIDS computer through the USB port.
4. The printer driver program should load itself. Answer the prompts as requested.
5. After the printer driver is finished loading, log off the computer as sysadmin and log back on under a user name.
6. Click on **Start Menu**, select **Settings** then **Printers**. Right click on the desired printer and select.
7. Set as Default Printer. Close Printer dialog box.
8. For each different user account, the default printer needs to be set up.

Change Date and Time

1. Log on to Windows as system administrator using **sysadmin** as the username and the current password.
2. Double click on the digital clock in the bottom right hand corner of the desktop screen.
3. Make corrections as needed on the Date/Time Properties window and click on **Done** when finished.



Install Software Upgrades

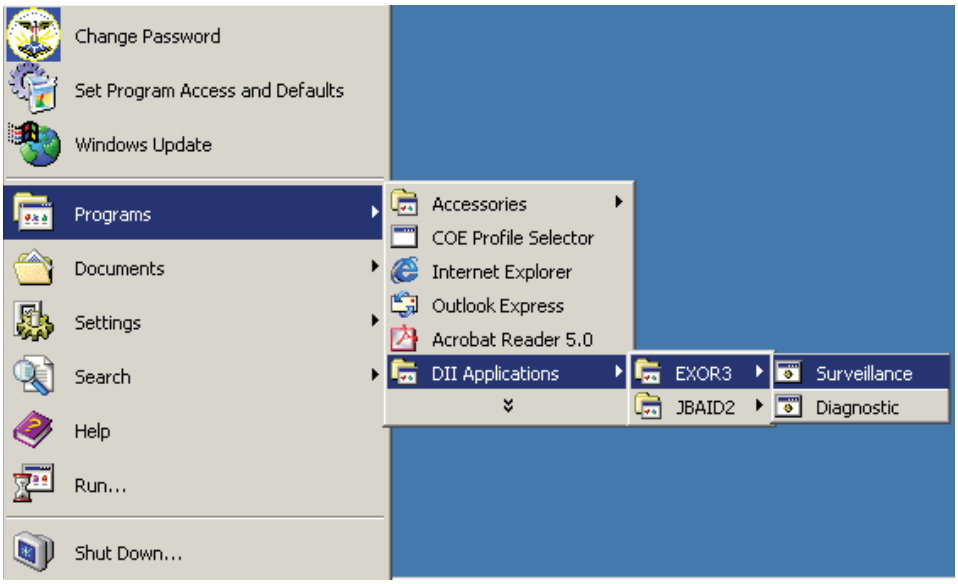
1. Log on to Windows as system administrator using **sysadmin** as the username and the current password.
2. Insert the JBAIDS software CD into the CD/DVD drive.
3. From the **Start** menu select **Programs/DII Applications/SysAdmin/Segment Installer**.
4. When prompted for the APM master authentication key, enter **apmauth**.
5. Follow instruction instructions as provided with the software.

STARTING JBAIDS SOFTWARE

The JBAIDS software features a database (Exor) where all of the test information is stored. The information includes analysis data, software preference settings, instrument information and more. The database is installed on the computer connected to the JBAIDS instrument. The database must be up and running on the desired laptop before the JBAIDS software can be used.

Note: Exor should be automatically started upon login to a JBAIDS laptop. If it auto-starts, then the system tray in the bottom right corner of the screen will contain two sets of paired red and green arrows, one for surveillance and one for diagnostic.

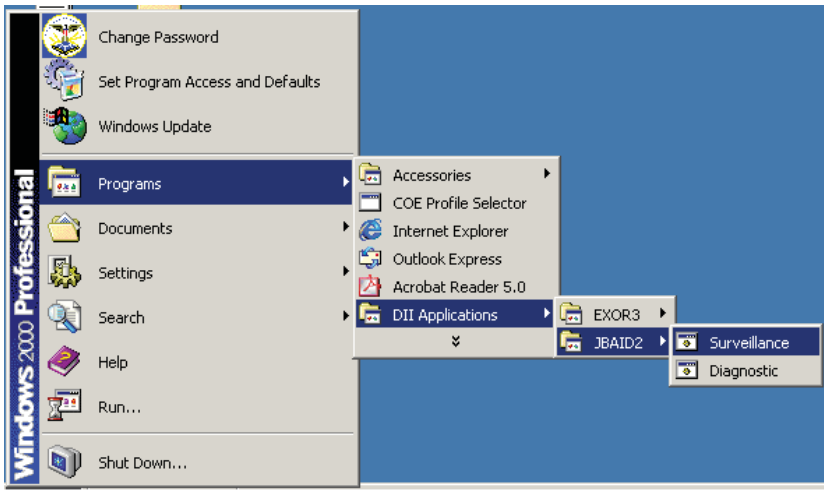
1. If Exor does not auto-start, locate the JBAIDS software program under the **Start Menu**, in the **Programs** folder, in the DII Applications/EXOR3 folder. Open the program called **Surveillance**.



2. Once Exor is opened, the icon will appear in the System Tray.

To start the JBAIDS software:

1. Locate the JBAIDS software program under **Start Menu, Programs** folder, DII Applications/ JBAIDS2 folder. Open the program called **Surveillance**.



2. Clicking **Start Test** (located to the left of the instrument picture) starts the Wizard.

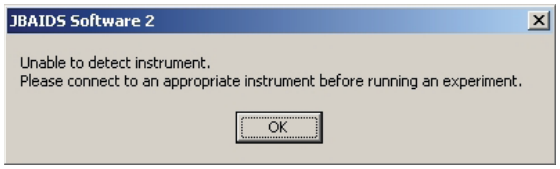
STARTING THE WIZARD

An operator of the JBAIDS instrument must execute a Wizard to run an analysis of samples. Advanced operators can also use the Wizard. The Wizard leads the user step-by-step through the process of selecting one or more pathogen targets (assays), entering the kit information, naming the samples, saving the test, loading the carousel, starting the run, viewing results, and printing a report.

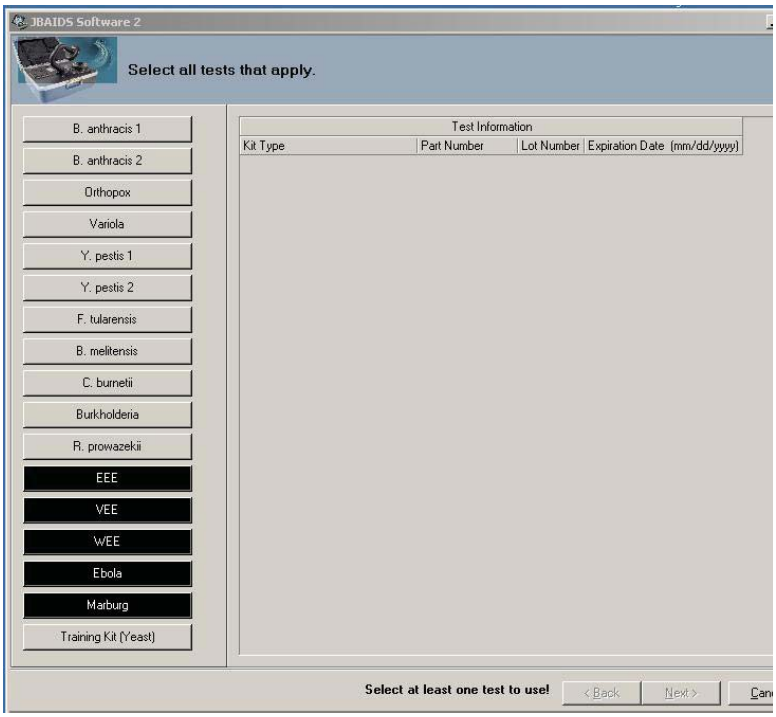
This section describes the Wizard windows and the user's workflow at each step.

1. Log in to the JBAIDS software. For instructions on starting the software, see "Starting JBAIDS Software" in the previous section.
2. The front window of the software is displayed.

1. Click **Start Test** to begin the Wizard.
2. If the software cannot find the instrument, see “Connecting to an Instrument” at the end of this chapter. If the software connects to an instrument, continue the steps below.


JBAIDS Software 2
Unable to detect instrument.
Please connect to an appropriate instrument before running an experiment.
OK

3. Once you identify the instrument, the next wizard screen will appear.
4. The Wizard displays a list of pathogen targets available for analysis.

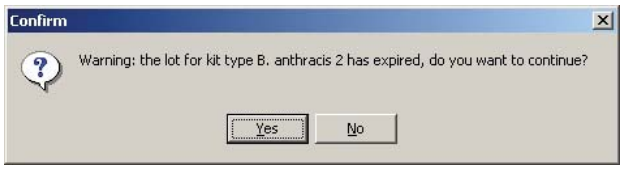


5. Click a test button for each pathogen target to be analyzed. You can select more than one pathogen target to be analyzed during a run. You can deselect a pathogen by clicking the target button.

Note: Selecting at least one RNA assay (black background with white lettering) will cause the Wizard to perform a reverse-transcription step and then proceed directly to PCR without user input. DNA and RNA assays can be run at the same time without detrimental effect to either.

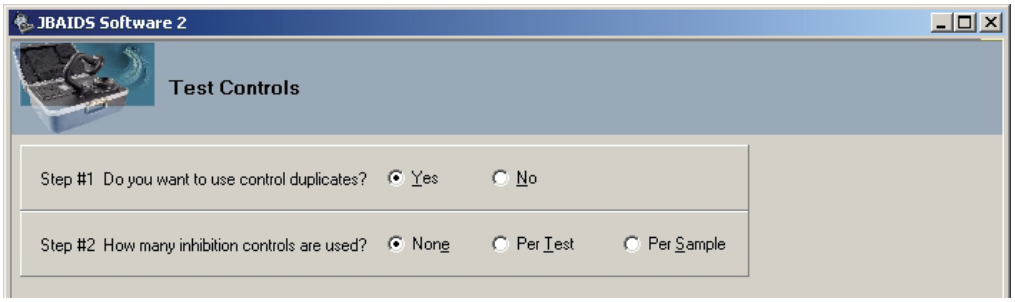
6. Enter the **Lot number** and the **Expiration Date** (printed on reagent box label) for each selected test. The software will automatically enter the Kit Type and the Part Number for each selected test.

Note: If you entered an Expiration Date that is passed, a message box appears that states that the reagents are expired.



7. Click **Yes** to confirm the decision to use the expired reagents. If expired reagents are used, the test report includes the statement “Expired Kits Used.”
8. Once all of the information is entered for each assay, click **Next**.

   The Test Controls window will appear.



9. The **Test Controls** asks for the following information:

   Step #1 Do you want to use control duplicates?
   The software automatically adds replicate controls: two positive and two negative controls for each pathogen assay.

   Yes—Default (highly recommended). This will organize the run with duplicates of positive, negative and inhibition controls.

   No

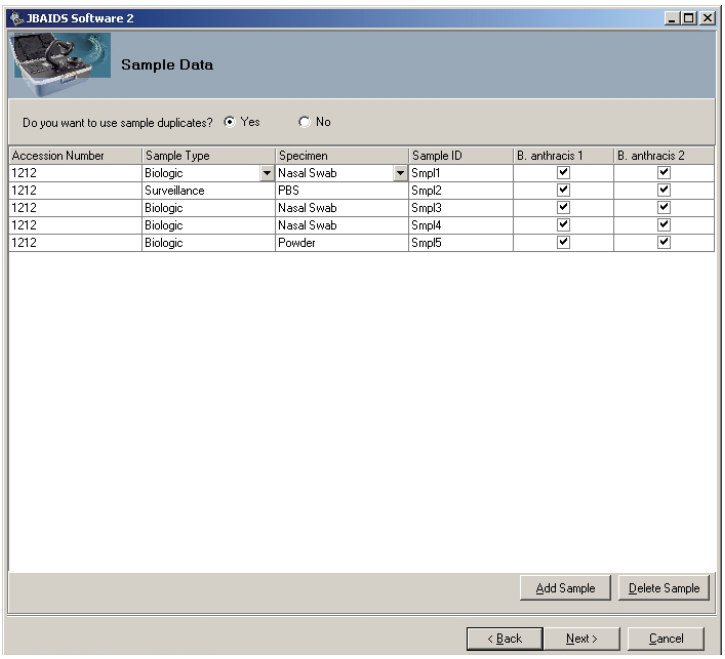
   Step #2 How many inhibition controls are used?
   Inhibition Controls are reagents with template (similar to positive controls) to which unknown sample is added. The software can determine whether an inhibitor is present in the unknown, which might lead to a false negative result (i.e. no target reported when it is actually present).

None	Default
Per Test	Select this if there are inhibition control(s) provided only for each assay selected regardless of the unknown sample number.
Per Sample	Select this if there are inhibition control(s) provided for each unknown sample.

10. Once the control information is entered, click **Next**.
11. The Sample Data window will appear. This window allows you to choose whether to use Sample Duplicates and to enter information about the samples that will be tested. Sample duplicates must be run with all (**Yes**) or none (**No**) of the unknown samples.

    Yes—Default (highly recommended). This will organize the run with duplicates of all unknown samples.

12. In this window, you also enter information about the samples that will be tested.



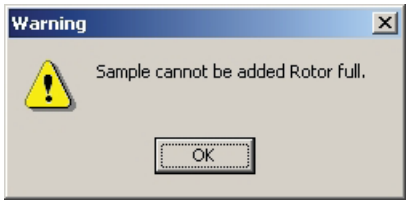
- To add a sample, click the **Add Sample** button located in the bottom right of the window.
- To delete a sample, select the desired sample and click the **Delete Sample** button in the bottom right of the window.

13. To each sample that is added, you will need to specify its characteristics. **Each Field Is Required.**
    - **Accession Number**
    - **Sample Type** (pull down menu options)
      Biologic
      Surveillance
    - **Specimen** (pull down menu options)

Whole Blood, FLOW	PBS, QFLOW	Gastric Washings, QFLOW	Ground Beef, FLOW
Whole Blood, QFLOW	Nasal Swab	Soil	Ground Beef, QFLOW
Serum	Surface Swab	Water, FLOW	Tuna Salad, FLOW
Plasma	Powder	Water, QFLOW	Tuna Salad, FLOW
Blood culture media	Sputum	Milk, FLOW	Lymph Node Aspirates
Culture Plate	Stool	Milk, QFLOW	Chicken, FLOW
Cultured liquid media	Pus Swab	Vegetable wash, FLOW	Chicken, QFLOW
PBS, FLOW	Gastric Washings, FLOW	Vegetable wash, QFLOW	Other

- **Sample ID—**Enter information to identify the specific sample. The default value is Smpl *n*, where *n* is the number of sample added.
- **Target check box—**There will be a check box for each pathogen target that was selected in the first window. Uncheck pathogens that are not being tested for certain samples. The software automatically calculates how many samples you will be running based upon the options you have selected. If you select a combination with too many capillaries you

will be warned with the following message. Use the **Back** button to make changes to your test or next to view the Load window.

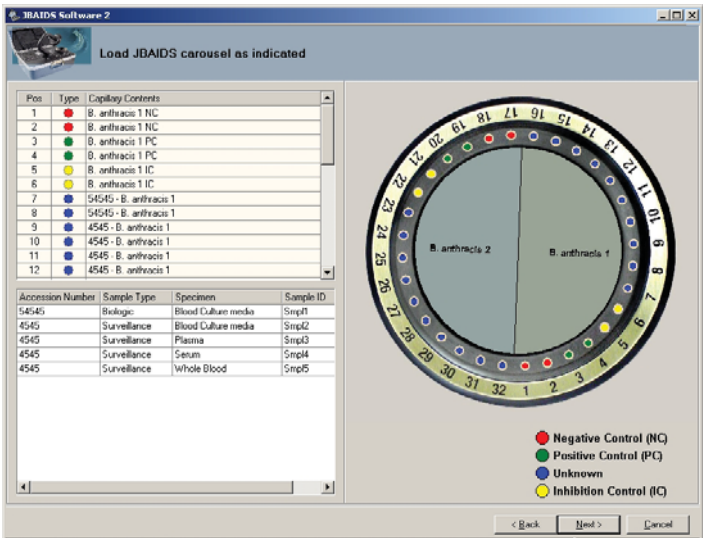


14. After all of the samples and their characteristics have been entered, click **Next** to display a loading window which illustrates the correct placement of capillaries in the carousel.

    The Wizard displays a sample list that includes the carousel position and the contents of each capillary.

    - Positive Controls are designated PC
    - Negative Controls are designated NC
    - Unknown Samples
    - Inhibition Controls are designated IC

    If you use IC controls, the software automatically enters IC per unknown sample or per test as designated in the Test Controls window.



15. Loading the Carousel

    a. Remove the carousel by giving it a quarter turn counter-clockwise to unlock it from the instrument. Lift the carousel straight up and out of the instrument to avoid breaking capillaries on the chamber fan. Appropriately discard capillaries from previous test.

    b. Load the prepared samples into the sample carousel using the Loading Window information as a guide. After the samples are carefully placed into the carousel make sure that all capillaries are seated correctly; they should be pushed down gently to seat them in the proper locations.

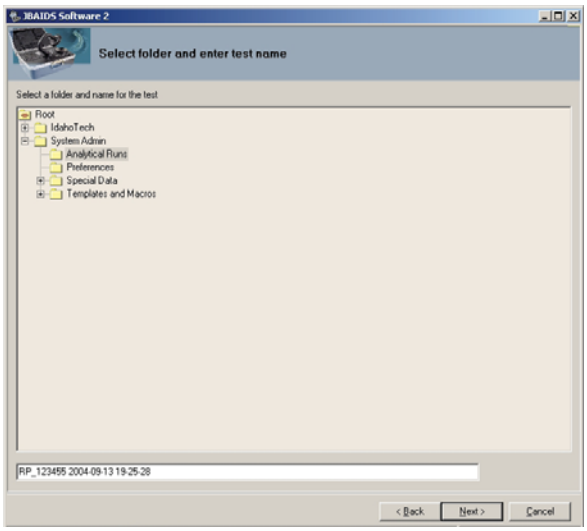
Note: ALL POSITIONS INDICATED BY THE SOFTWARE WIZARD MUST CONTAIN A FILLED CAPILLARY. If the instrument does not detect a capillary in a position designated to have a capillary, the run will abort. An empty capillary will also cause the run to abort; ensure that reaction mixture has been forced into the bottom of each capillary after centrifugation.

c. Replace the loaded carousel into the instrument by aligning the gold arrows on the outside of the carousel and the deck plate.
d. Lock the carousel into place by giving it a quarter turn clockwise.
e. Rotate the heating duct assembly over the samples to perform a test.

WARNING: If capillaries are not properly seated, the fluorimeter readings may be excessively noisy, causing uncertain, invalid or erroneous readings. Do not force the capillaries, which can break them. Lock the carousel into the instrument by aligning the gold arrows and rotating it clockwise to its locked position.

16. With the carousel locked into place and the heating duct (snorkel) assembly in its closed position, click **Next**.

    The next screen prompts you to save the test.



17. Save the test in the Analytical Runs folder under your **Navigator** user folder. The default name for the test is the Instrument ID, plus the current date and time in Universal Time (Greenwich Mean Time).
18. Keep the default location and name, or select a new location and/or enter a new name.
19. Click **Next** to save the test. Make sure the carousel is in its locked position and the heating duct (snorkel) assembly is positioned correctly over the carousel. Click **Start Test** to begin the run. The instrument will begin cycling.

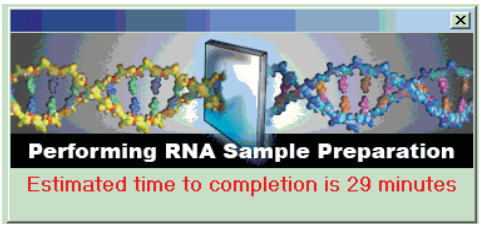
JBAIDS Run Wizard
Your test is now ready.
Close the JBAIDS snorkel, then click Start Test to begin the run.
Start Test
Cancel

Note: If a sample is not found during the run, then the run will abort. Use the following steps to troubleshoot:

- Replace any missing capillaries with appropriate samples.
- Check that your samples have been centrifuged down to the bottom of the capillary and volumes are roughly equivalent between all capillaries.
- Ensure that all capillaries are firmly seated and carousel is locked into place.
- Wipe down the capillary with lens paper to remove any fingerprints or smudges.
- If none of these apply: replace any capillaries that failed with newly prepared freeze-dried reagents (the same sample extraction can be used).
- Return to the Front Screen, then repeat **Start Test** .

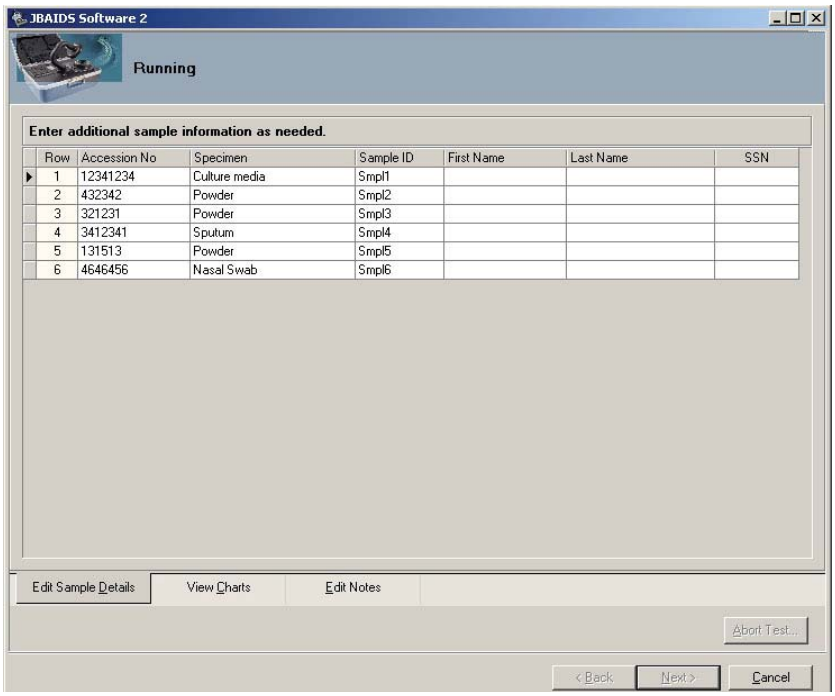
Note: If you need to stop the analytical run before it is finished (e.g. capillaries breaking), click Abort Test. When you abort a test, the data for that test will not be available for analysis, but can be viewed in the Summary Module Raw Data tab (see “Analysis Mode” in this chapter).

20. If an RNA assay is chosen in the first Wizard screen, then after the run is started, the RNA Sample Preparation begins. A countdown timer is shown for RNA Sample Preparation. When RNA preparation is over, the PCR amplification will begin without any user input required. Both RNA and DNA assay can be run with the RNA Sample Preparation step without detrimental effect to either.

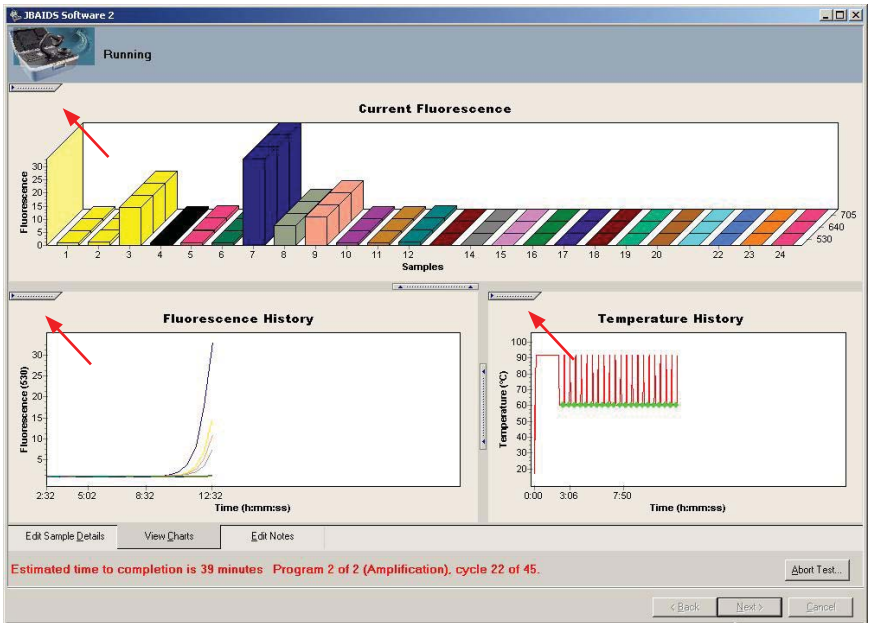


a. During the test, the **Running** window is displayed. On the bottom left of this window there are three tabs that display windows, which contain critical information about the samples in this test.

b. The **Edit Sample Details** tab is the default tab and is shown below. This window allows you to enter additional information about each sample including, Social Security Number, First and Last Name.

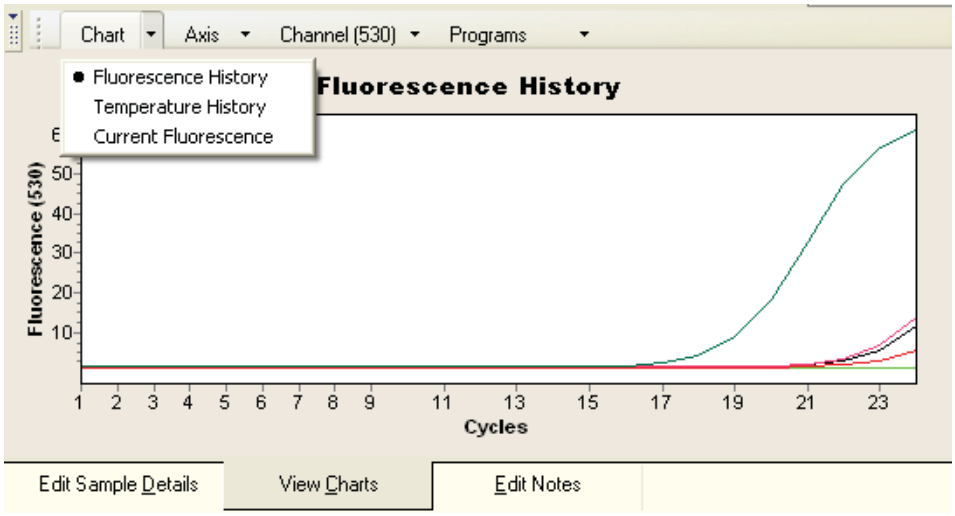

JBAIDS Software 2
Running
Enter additional sample information as needed.
Row | Accession No | Specimen | Sample ID | First Name | Last Name | SSN
1 | 12341234 | Culture media | Smpl1
2 | 432342 | Powder | Smpl2
3 | 321231 | Powder | Smpl3
4 | 3412341 | Sputum | Smpl4
5 | 131513 | Powder | Smpl5
6 | 4646456 | Nasal Swab | Smpl6
Edit Sample Details
View Charts
Edit Notes
Abort Test...
< Back
Next >
Cancel

c. The **View Charts** tab displays charts of data in real-time as it is returned by the instrument during the analytical run. It allows users to select which charts they want to see.

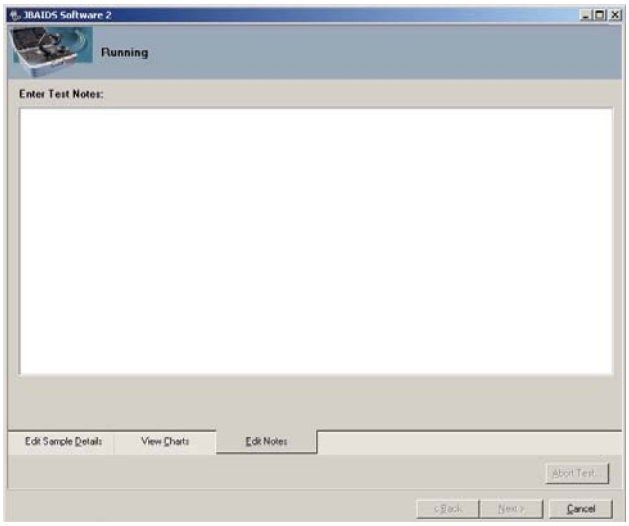


d. To select a chart, click the handle (see arrows in picture) in the left corner of the desired chart, then from the Chart menu, select one of the three available chart types:

- Fluorescence History
- Temperature History
- Current Fluorescence

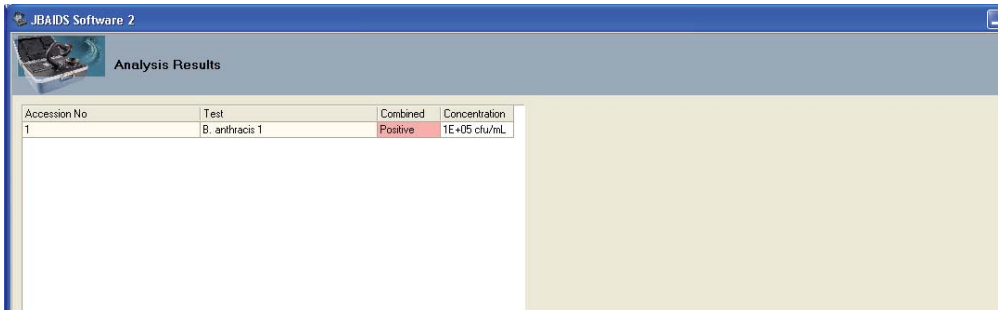


20. To enter additional information about the analytical run, click the **Edit Notes** tab (shown below).



21. When the test is finished, the message **Run Complete** will appear in the bottom of the window. Click **Next** to view the results.

    The Analysis Results window is shown below.



22. For each sample, the results include the following:

    - **Accession No.**
    - **Test—**pathogen target.
    - **Combined Result—**is a combination of the control results and the unknown results. See chart below.
    - **Concentrations—**quantification results for certain positive samples (specific target/specimen combinations) including appropriate units. Concentration is only available to advanced operators.

    The Results window displays results only for the capillaries that contain unknown samples.

    The possible combined results include the following:

Positive	**A red positive call indicates that the target was identified in that sample and the run controls were successful. A sample that is detected as positive will generate an audible signal in the software.**
Negative	**A green negative call indicates that the target was not identified in that sample and all the run controls (NC, PC and IC) were successful.**
Uncertain	**A yellow uncertain call indicates that the instrument was unable to interpret the data and the run controls were successful.**
Invalid	**A yellow invalid call indicates that a PC or NC failed. All samples connected to that control would be invalid.**
Inhibited	**A yellow inhibited call indicates that the PC and NC were successful and one or more inhibition capillaries associated with that sample failed.**

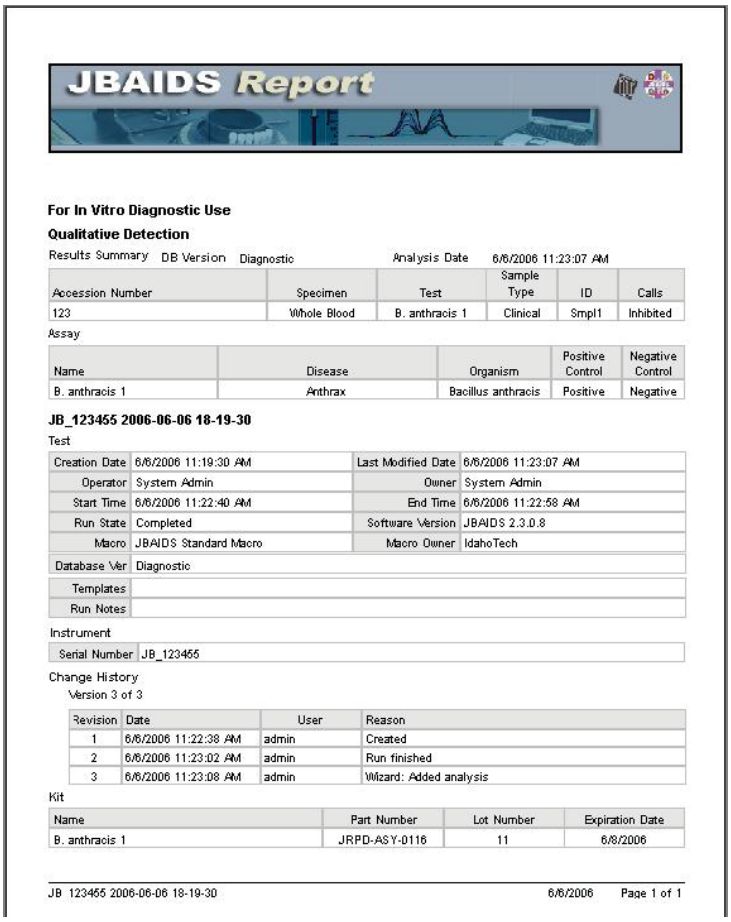
    Positive, Invalid, Inhibited, and Uncertain results should be referred to a supervisor or advanced operator for appropriate follow up. Additional information regarding follow-up actions may be included in product inserts.

23. Click **Finish** to view a report of the test results.

Test Report

The report contains the following information:

- Qualitative Detection Module (analysis of the run, see Analysis Mode section for more details)
  - Results Summary including results for each unknown
  - Assay information including results for each assay's controls
- Test information (such as name and date)



JBAIDS Report

For In Vitro Diagnostic Use

Qualitative Detection

Results Summary DB Version Diagnostic Analysis Date 6/6/2006 11:23:07 AM

Accession Number	Specimen	Test	Sample Type	ID	Calls
123	Whole Blood	B. anthracis 1	Clinical	Smpl1	Inhibited

Assay

Name	Disease	Organism	Positive Control	Negative Control
B. anthracis 1	Anthrax	Bacillus anthracis	Positive	Negative

JB_123455 2006-06-06 18-19-30

Test

Creation Date	6/6/2006 11:19:30 AM	Last Modified Date	6/6/2006 11:23:07 AM
Operator	System Admin	Owner	System Admin
Start Time	6/6/2006 11:22:40 AM	End Time	6/6/2006 11:22:58 AM
Run State	Completed	Software Version	JBAIDS 2.3.0.8
Macro	JBAIDS Standard Macro	Macro Owner	IdahoTech
Database Ver	Diagnostic		
Templates			
Run Notes			

Instrument

Serial Number	JB_123455

Change History

Version 3 of 3

Revision	Date	User	Reason
1	6/6/2006 11:22:38 AM	admin	Created
2	6/6/2006 11:23:02 AM	admin	Run finished
3	6/6/2006 11:23:08 AM	admin	Wizard: Added analysis

Kit

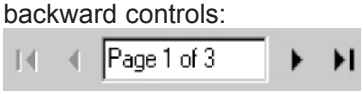
Name	Part Number	Lot Number	Expiration Date
B. anthracis 1	JRPD-ASY-0116	11	6/8/2006

JB 123455 2006-06-06 18-19-30 6/6/2006 Page 1 of 1

- Run protocol
- Sample information
- Instrument information including serial number
- Kit name, part number, lot number, and expiration date
- Analysis results and charts

Advanced operators can customize the report by selecting which information items to include and by changing the item order. Report information options are selectable on the left menu option window.

Online reports cannot be saved. However, you can recreate a report easily by saving the report customization settings and then regenerating the report whenever you need it. See the procedure below for more information.

Report Controls for All Users	**Report Controls for Advanced Operators**
To see additional pages of the report, use the page forward and backward controls:  To change the scale of the report within the window, click one of the following buttons: • The first button displays the report at its printed size. • The second button fits the entire report page into the window. • The third button fits the width of the report page into the window. To print the report, click **Print** at the top of the report window. 	The left side of the report work pane contains a list of available items; checked items are included in the report. The order of items in the list determines the order of items in the report. Check the boxes for the items in the list that you want to include in the report. To change the location of an item in the report, click and drag the item to a new location in the list. **Note:** You cannot drag an item into a category where it does not belong. For example, you cannot drag results from a melting temperature analysis into an absolute quantification analysis. • To save the report settings, click **Save Settings**. • The next time you generate a report from this analysis, the report will be created using the content and order of items you specified. • To remove the saved settings, click Default Settings • The next time you generate a report from this analysis, the report will be created using default settings.

1. Click **Print** to print the report.
   You cannot modify the report content or display. You cannot save the report separately; it must be recreated from the test.
2. If changes must be made to a completed test (e.g. adding sample information) then close the report, open the desired test and perform edits. Save the test and regenerate the report by clicking **Report** on the Global Toolbar**,** or selecting **Report** from the **File** menu.

To generate a report from a previous test

1. Open the analytical run and make any necessary edits.
2. Click **Save.**
   IMPORTANT: You must save the run before you can create an analysis report.
3. Click **Report** on the Global Toolbar**,** or select **Report** from the **File** menu.
   - The report window opens in the work pane and can be modified as above.
   - After a run, some fields can be edited by advanced operators. To edit the fields, close the report, edit the specific fields and regenerate the report.

ANALYSIS MODE

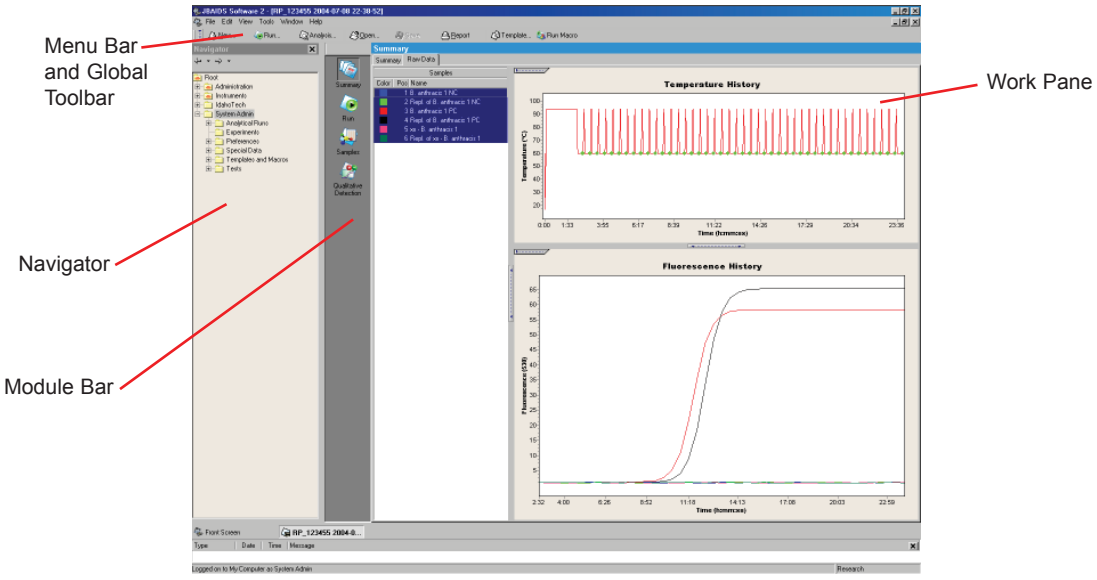
Follow the procedure below to open a demonstration analysis included with JBAIDS software. This demonstration illustrates the features and components of the JBAIDS software described in the rest of this chapter. (You do not need to be connected to instrument to view or edit the demonstration analysis).

To view the summary window of a demonstration test

1. Log on to JBAIDS software.
2. To open the **Navigator:** from the **View** menu, select **Navigator.** Click the plus sign (**+**) next to the Analytical Runs folder.
3. Double-click the run name to open the test in the software window.
4. Double-click the **Summary module** in the Module Bar (column to the left of the work pane) then select the **Raw Data** tab.
   The tab displays a list of samples and charts of test data.

Understanding the JBAIDS Test Software Window

The figure below illustrates the **Raw Data** tab of the software window containing information from a demonstration test.



The software window contains the following areas:

- **Navigator**: The **Navigator** tree structure organizes and displays information about users, instruments, and data.
- **Menu Bar:** The menu bar contains menus to access and perform software functions.
- **Global Toolbar**: The global toolbar at the top of the window contains buttons for common tasks.
- **Work Pane**: The work pane is used to perform the specialized operations of the software, such as programming the analytical run, viewing data, or analyzing results.

- **Module Bar**: The module bar provides access to the components of a test. The module bar is visible only when a run is opened for viewing.
- **Task Bar**: The task bar displays icons for all open windows, including ones “hidden” behind the current window.
- **Status Bar:** The status bar displays the name of the current user and computer.
- **Messages Window**: The message window displays any messages generated as you use the software.

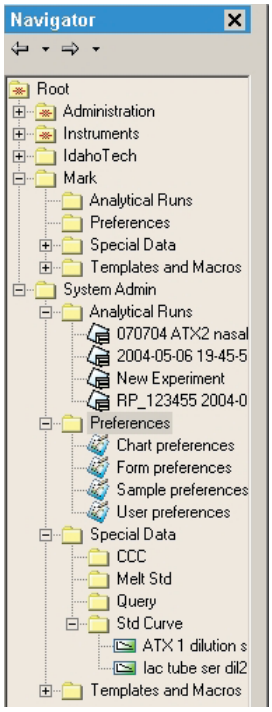
  The Global Toolbar, Task Bar, Status Bar, Navigator, or Messages Window can be viewed or removed by selecting or de-selecting desired object under **View** menu.

The following sections describe the main areas of the JBAIDS software window in more detail.

The Navigator

The Navigator on the left side of the JBAIDS software window provides access to items stored in the JBAIDS software database. Items include tests, user accounts, instruments, macros, user preferences, etc. In the Navigator, items are organized in folders in a tree structure. The Navigator always includes the following default folders and items:

- The **User** folders contain default subfolders, such as a folder for analytical runs, preferences, special data, templates and macros. Users can also create their own subfolders.
- An **Idaho Technology** folder that contains Analytical Runs, Run Templates, and Experiment Macros. This folder can be used by anyone with access to JBAIDS software. (To modify an item, you must first copy it to your own user folder.)
- An **Instruments** folder that contains an icon that represents each JBAIDS instrument added to the software database.
- An **Administration** folder that contains user groups, user roles, user accounts, and security policies. The Administration folder is visible only to an advanced operator and is not editable.



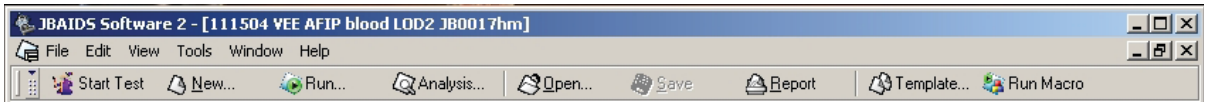
To show or hide items under a folder

1. Double-click the folder name or click the plus (+) or minus (-) sign next to the folder.
2. To close the Navigator
   - From the **View** menu, deselect **Navigator** or
   - Click the **X** in the upper right corner of the Navigator pane.
3. Closing the **Navigator** causes the work pane to extend the full width of the window.

To reopen the Navigator

1. From the **View** menu, select **Navigator.**
2. Right-clicking on an object in the **Navigator** allows you to delete, copy, rename or create a new folder, depending on the object type and user's permissions.

The Menu Bar and Global Toolbar


JBAIDS Software 2 - [111504 VEE AFIP blood LOD2 JB0017hm]
File Edit View Tools Window Help
Start Test New... Run... Analysis... Open... Save Report Template... Run Macro

Keyboard shortcuts for many of these steps are available and are listed to the right of the process.

Use the **File Menu** to

- Create (New), Open, Save, and Close items.
- Import files into the designated database. Export copies files from software database and saves them to another location.
- Batch Import and Batch Export allows you to move directories of files into or out of the database.
- Open an analytical run Report.
- Print the current window.
- Exit the software.

Note: Logout of JBAIDS software is disabled in the system. An attempt to logout will return user to front window.

Use the **Edit Menu** to

- Cut, Copy, and Paste data in the work pane or items in the **Navigator**
- Select All items

Use the **View Menu** to

- Display or hide sections of the JBAIDS software window. The Global Toolbar, Task Bar, Status Bar, Navigator or Messages Window can be viewed or removed by selecting or de-selecting the desired object under **View** menu.
- Display the Front window (the window you see when you start JBAIDS software) in the work pane.

Use the **Tools Menu** to

- Create Macros/Kits or Templates based on an item currently open in the work pane.
- Run Macro/Kit.
- Apply Template to object open in work pane.
- Manage Known Instruments, providing information about all instruments that have been connected to the database.
- View Database Status (for advanced operators only). This provides a list of logged in users and information about the Query Engine. See “Updating the Database” later in this chapter.

Use the **Window Menu** to

- Close, Minimize All, and arrange windows (Cascade, Tile Horizontally, Tile Vertically) when multiple windows are open in the work pane.
- Select an open window to make it the active window. (The bottom of the Window menu displays a list of all currently open windows. The active window is checked.)

Use the **Help menu** to

- Display online versions of JBAIDS software manuals (Content)
- View version and copyright information about the software

Using Toolbar Buttons

The buttons in the toolbar provide quick access to many commands that are also available in the menus. If a button is inactive (dimmed) it may be because you do not have the necessary permission to perform the task or because that task does not apply to currently open object.

The global toolbar contains the following buttons:

Click **Start Test** to begin the wizard.

Click **New** to create a new item. A dialog box displays icons for all available items. Select the item desired.

Click **Run** to open the Run module so you can create parameters for a new test.

Click **Analysis** to add a new analysis module to an existing test. A dialog box displays a list of available analysis modules. The Analysis button is enabled only when a test is active in the work pane.

Click **Open** to open any item. A file list opens so you can select the item you want. (You can also double-click an item in the main Navigator to open it.)

Click **Save** to save changes made to an item. The Save button is enabled only when the item in the active window has been modified.

Click **Report** to open a test report window.

Click **Template** to apply a predefined template to the currently active item. A file list opens so you can select the template.

Click **Run Macro** to run a predefined macro. A file list opens so you can select the macro.

The Work Pane

The JBAIDS software work pane contains information specific to the operation you are performing. For example, when an advanced operator runs a test the work pane displays a Run window that includes the Programs tab with the analysis protocol, a tab that displays the current data being generated (Online Data Display), and a Run Notes tab.

The work pane is designed to allow multiple open windows. A label for each open window is visible in the Taskbar at the bottom of the window.

To view and size windows in the work pane

- Use the mouse pointer to drag a window's edge or corner to resize the window.
- Use the buttons in the upper right corner of each window to maximize, minimize, restore, or lose the window.
- Use the **Window** menu to close, minimize, or arrange the windows.
- Click the label in the Taskbar to restore a minimized window or to bring a hidden window to the front.

To size individual sections of Windows

- Drag the horizontal borders between sections to size them.
- Click the handle on the border of a section to hide or show the section. To size individual charts see *Zooming and Panning* later in this chapter.

The Module Bar

The module bar contains icons for analysis and run components. The bar is visible only when an analytical run is open. The module bar displays the following icons:

Summary icon Opens the Summary module of the run, which contains information about the run such as name, date, and owner (Summary) and charts of **Raw Data** generated by the run.

Run icon Opens the Run module, which includes the details of the run protocol (Programs), charts of analytical run data (Online Data Display), and Run Notes entered by the person running the test.

Samples icon Opens the Sample Data, which contains sample information needed for the run. Capillary View contains information about replicate positions, sample names, assays tested, sample ID and any sample notes. Qual Detect contains specific information for the Qualitative Detection Analysis including control positions and types. Adding other analyses will create tabs in the sample module with analysis specific information.

Analysis icons Opens the associated analysis module. When an analysis is added to a test, an analysis icon is added to the module bar. This example shows an icon for an Absolute Quantification analysis.

To use the module bar

- Click an icon to open the module.
  Or
  Use the keyboard shortcut for the icon, Ctrl+Shift+*N*, where *n* is the number of the icon counting from the top. For example, the Samples icon is always third in the list of icons, so to open the **Sample Data** module, press Ctrl+Shift+3.
- Hold the mouse pointer over an icon to see the name of the related module and the keyboard shortcut for opening the module.
- Right-click the module bar, then select New Analysis to add an analysis module to a test. (The right-click menu is not available to users with the operator role.)
- Right-click an analysis icon to display a menu that lets you
  - Remove the current analysis from the test.
  - Rename the current analysis. Renaming is helpful if you have more than one analysis of the same type, such as two Qualitative Detection analyses.

  (The right-click menu is not available to users with the operator role.)

Copying Items

You can copy an item from another user's folder into your own folder or subfolder. (However, your user role may limit which other users' folders are visible to you.)

Once the item is in your own folder, it becomes your item and you can modify it as necessary (subject to the limitations of your user role). For example, you might want to copy a template from another user's folder into your own Templates folder and then modify it.

To copy items from another user's folder

1. Right-click the item you want to copy in the **Navigator,** then select **Copy.**
   A file list opens.
2. Select your user folder (or a subfolder under your user folder), enter a new name for the item if desired, and then click **OK.**

Renaming and Deleting Items

Note: Only advanced operators can rename or delete items.

To rename an item

1. Select the item in the Navigator, then press **F2.** The item name becomes an editable text box.
   Or
   Right-click the item in the **Navigator,** then select **Rename**.
2. Type the new name of the item.

To delete an item

1. Select the item in the **Navigator,** then press the keyboard **Delete** key.
   Or
   Right-click the item in the **Navigator,** then select **Delete.**
2. Click **OK** to confirm the deletion.

Importing and Exporting Files

To view analytical run information in JBAIDS software, the test file must be stored in the JBAIDS software database. Therefore, if run files (such as files from a previous version of JBAIDS software) are currently stored on a hard drive or a flash drive, you must *import* the files into the database. Importing a file copies the file into the database; it does not remove the file from the original location.

Importing Selected Files

You can import one or more selected files by using the **Import** command on the File menu or by dragging and dropping files from Windows Explorer.

To use the Import command to import files

1. From the JBAIDS software **File** menu, select **Import,** then select the type of file you want, as follows:
   - For JBAIDS software files, select **Object .ixo Files.** All JBAIDS files have the extension **.ixo**
   - For **.flo** files (from instruments such as the RAPID or LightCycler), select **ATF Files.**
   - For **.cof** files (for external standard curve files) select **COF Std. Curve Files.**
2. Select the files you want to import.

   To select multiple files, press **Ctrl** while selecting the file names, or press **Shift** to select consecutive files.
3. Click **Open.**

Note: These files have been imported into the software, but have not been saved in the JBAIDS database.

4. To save the currently displayed file in the JBAIDS software database, click **Save,** select the folder where you want to store the file, then click **OK.** A file cannot be saved to a folder in which it already exists; therefore, it must be renamed or the original file replaced with the new file.

5. To save each of the remaining imported files (if any), click the file name in the task bar to make the file active in the work pane; click **Save,** select a folder, then click **OK.**

Note: When you save an analytical run that includes color compensation, the associated color compensation file is saved automatically in the CCC subfolder of your Special Data folder.

To use the drag-and-drop method to import files

1. Open **Windows Explorer,** then find and select the files you want to import.
   To select multiple files, press **Ctrl** while selecting the file names.
2. Drag the files onto the **Navigator** (any location within the **Navigator** border will do. When selecting **ATF Files (.abt, .tmp, .flo)**, each file must be dragged).
   The first of the imported files is opened in the work pane. The names of the other files are displayed in the task bar.
3. To save the currently displayed file in the JBAIDS software database, click **Save,** select the folder where you want to store the file, then click **OK.**
4. To save each of the remaining imported files (if any), click the file name in the task bar to make the file active in the work pane; click **Save,** select a folder, then click **OK.**

Importing a Directory of Files

To import a directory of files

1. From the JBAIDS software **File** menu, select **Batch import.**
   The Batch import dialog box is displayed.
2. Click **Add.**
3. Find and select the directory you want to import, then click **OK.**
   The directory path is added to the window.
4. Check **Include subdirectories** if you want to include the subdirectories of the directory.
5. Repeat Steps 2–4 to add additional directories as needed.
6. If you need to remove any of the paths you have added
   - Click in the **Remove** column for the file. A gray button is displayed.
   - Click the button to remove the file.
7. Repeat process to add more directories.
   When finished adding directories, click **Next.**
8. Select the folder in the database in which to store the imported files, then click **Next.**
9. Select type of file to import. The default (no box checked) is JBAIDS files or **.ixo**. Check the box next to **ATF** or **COF** if these types are being imported.
10. Select the action for duplicate files**.**
11. The next tab will display the current status of the imported files. Any failed imports will have information reported in the Messages column. Maximizing the window and resizing the columns will allow you to read long messages. A file cannot be added to a folder in which it already exists.
    When all the files have been imported, view results on the **Import done** tab.
12. To redo the import with different import parameters:
    - Click **Previous** twice to return to the **Start Import** tab.
    - Click **Reset.**
    - Change the parameters you want, then click **Next** to re-import the files.
13. When finished, click **Done** on the **Import done** tab to close the dialog box.

Exporting JBAIDS Software Files

Note: Changing the name when a file is exported does not change its name in the database. When the desired file is imported into the database it will retain its original name. If you desire to change a file name, rename it in the database before exporting.

To export a JBAIDS software analytical run or other item

1. In JBAIDS software, open an analytical run or other item you want to export.

Note: The item must be open in the work pane before you can export it.

2. From the **File** menu, select **Export.**
3. Navigate to a location to save the exported file, select **XML Object Files (.ixo)** as the file type, and enter a new file name or keep the existing name (see note above), then click **Save.**
   The file is saved with an **.ixo** extension.

To export JBAIDS software analytical run raw data

1. In JBAIDS software, open the run containing the data you want to export.

Note: The item must be open in the work pane before you can export it.

2. From the **File** menu, select **Export.**
3. Navigate to a location to save the exported data, select **Raw data file (.txt)** as the file type, enter a new file name (or keep the existing name), then click **Save.**

   The text file contains the raw fluorescence and temperature values for each data acquisition point in the analytical run. You can use any text editor, such as Notepad, to open the file.

Creating and Running a Test (Available Only to Advanced Operators)

To create a protocol and run the test

1. Turn on the computer and the JBAIDS instrument.

Note: Be sure the instrument is powered on before you start the software.

2. Login as an advanced operator and start the **JBAIDS software**.
3. Click **Run** in the global toolbar.
   The Programs tab of the Run module is displayed.
4. In the **Programs** section, define one or more test programs. For each program, define the number of cycles, analysis mode, and temperature targets. Programs and targets can be added and deleted by using the + and – signs. You can move between programs or targets by using the up or down arrows. For each target you must specify temperature, hold time, ramp rate, and fluorescence acquisition mode.
5. Load capillaries into the instrument carousel.
6. Click Samples module to enter sample name, ID, assay, sample notes, etc.
7. Click **Start Run** to begin the run and monitor data as it is gathered from the instrument.
8. When prompted, name and save the run.

9. Select the charts you want to view as the test runs.
10. Add any additional information in the **Run Notes** tab.

Tip: All users can edit sample information before and during a run. Advanced operators can edit some fields (sample notes, sample name and information and sample ID) after a run is completed. To edit sample information after a run, go to the sample module and edit the desired sample information. Save the test and regenerate the report.

11. All data is automatically saved at the end of the run.

Analysis Modules

The JBAIDS software includes several analysis modules you can use to analyze test results. To analyze a test, you must add the appropriate analysis module to the test after it has finished running. The Wizard automatically adds a Qualitative Detection module to each run.

Absolute Quantification: Calculates the concentration of target DNA in unknown samples, based on the concentration of standard samples from the same run.

Qualitative Detection: Determines whether a target sequence is present in unknown samples.

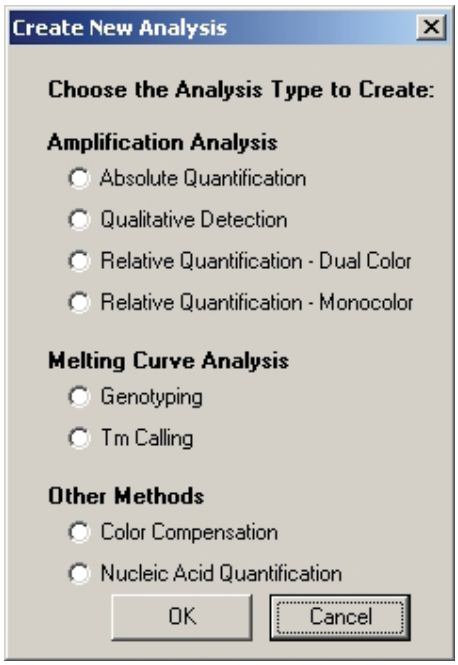
Relative Quantification (Mono-Color and Dual-Color): Compares the ratio of two sequences in unknown samples to the ratio of the same two sequences in known samples.

Genotyping: Defines genotype groups based on melting temperature profiles.

Tm Calling: Calculates the melting temperatures, melting peaks, and peak areas of unknown samples.

Color Compensation: Generates color-compensation data used to compensate for overlap between fluorescence channels in a multicolor run.

Nucleic Acid Quantification: Calculates the concentration of target DNA in unknown samples by comparing each



Summary of Steps

The general steps required to add an analysis module are described below. The steps are the same for any analysis type.

Note: Users must be advanced operators.

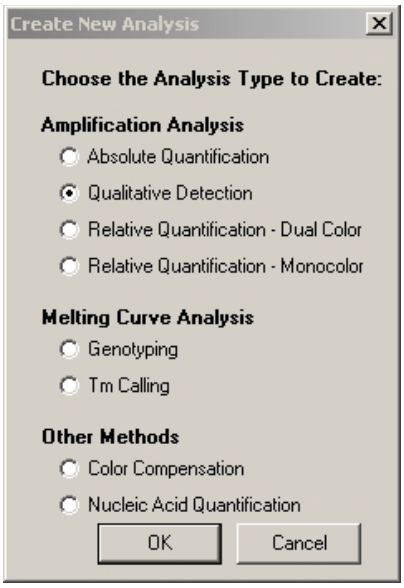
To perform an analysis

1. Open the analytical run you want to analyze.
2. Click **Analysis** on the global toolbar.

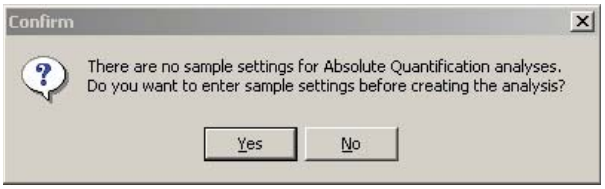
Note: If the Analysis button on the toolbar is grayed out, your user account is not the advanced operator; you cannot add an analysis to the test.

The Create New Analysis dialog box opens.

3. Select desired analysis type, then click **OK**.

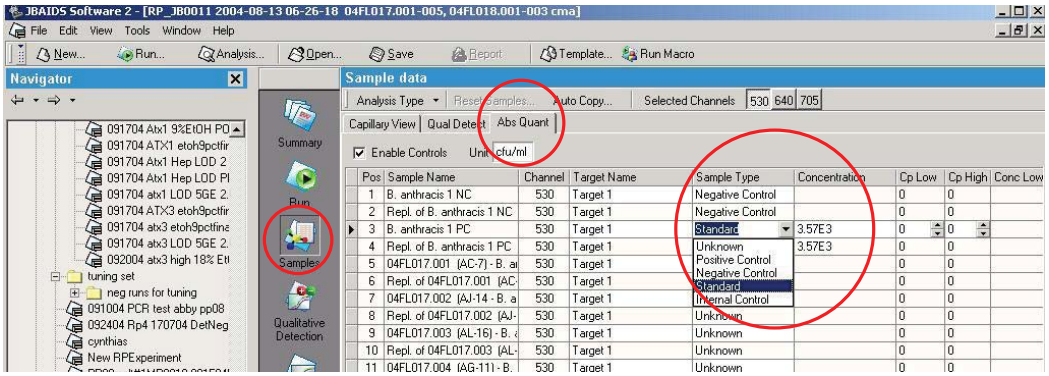


When the dialog box opens with the question “Do you want to enter sample settings before creating the analysis select, **Yes**” This will take you to the **Sample Module**.


Confirm
There are no sample settings for Absolute Quantification analyses.
Do you want to enter sample settings before creating the analysis?
Yes
No

4. In the **Sample Module** enter information about each sample in the **Capillary View** tab as well as the channels to be used in the analysis.

Select the analysis-specific tab next to the **Capillary View** tab and enter information for the analysis. If an analysis specific tab does not appear then select the correct type from the Analysis Type drop-down menu at the top left of the work pane. An example from **Absolute Quantification** is shown below.



5. Again click **Analysis** on the global toolbar, or right-click the **module bar,** then select **New Analysis.**
   The Create New Analysis dialog box opens as above.
6. Select the analysis type you want, then click **OK.**

Note: If desired, you can manually add an analysis-specific module to the Sample Data before or during a test run.

Note: Certain types of analysis require specific sample information in order to generate results. Failure to enter this information will prevent results from appearing in analysis module.

7. Click the analysis icon in the **module bar** to open the analysis window.

Note: If you change the analysis-specific information in the Sample Data after performing the test, the analysis results are recalculated using the updated values from the Sample Data.

8. Repeat **Steps 2–7** to perform additional analyses.
9. Click **Save** to save the analysis results as part of the analytical run.

PERFORMING A QUANTIFICATION ANALYSIS

A quantification analysis can be performed on a test containing an amplification program. The analysis uses sample *crossing points* (Cp) to determine the presence, concentration, or relative concentration of target DNA in unknown samples after amplification.

Understanding Sample Crossing Points

In an amplification reaction, the cycle at which the fluorescence of a sample rises above the background fluorescence is called the Cp of the sample. The Cp of a sample appears as a sharp upward curve on the test's fluorescence chart. The Cp is the point at which amplified product is first visible in the data. The presence of a Cp indicates that target DNA is present.

A sample's Cp is expressed as a cycle number. The value depends on the initial concentration of DNA in the sample. A sample with a lower initial concentration of target DNA has a higher Cp because it requires more amplification cycles to reach the Cp. A sample with a higher concentration has a lower Cp because it requires fewer cycles.

How Cps are used in a quantification test depends on the type of analysis (Absolute Quantification or Qualitative Detection).

JBAIDS Quantification Analyses

To analyze the data, a quantification analysis module considers fluorescence values measured in the exponentially growing phase of the PCR amplification process. This phase is termed the **"log-linear"** phase because the points making up this exponential curve are converted to a linear curve upon logarithmic plotting.

There are two JBAIDS quantification analyses:

Qualitative Detection: Determines whether a target sequence is present in unknown samples by providing Detector calls on completed 45 cycle runs. Can also determine whether unknown samples have inhibitors present if Inhibition Controls are used. For some samples, it can provide concentration estimates. The JBAIDS Wizard automatically adds a Qualitative Detection Analysis to all Wizard runs.

Absolute Quantification: Calculates the concentration of target DNA in unknown samples, based on the concentration of standard samples. It can also determine whether samples have Cps or concentrations within an expected range.

QUALITATIVE DETECTION ANALYSIS

The Qualitative Detection module analyzes unknown samples for the presence of a particular target, based on whether the data shows target amplification. The analysis can also quantify the amount of target DNA for designated assay and specimen combination. A Qualitative Detection analysis is automatically added to any run performed with the Wizard.

Controls

Control reactions provide information about the presence of the target, inhibitors in samples, contamination as well as information about the quality of the reagents, PCR process and reaction conditions. Controls are expected to behave in a certain way, depending on their type and other user-specified information. If they fail to behave as expected, the unknown samples are considered failures.

The following types of controls are used in a Qualitative Detection analysis:

Positive control (PC): Contains the DNA target for which the unknown samples are being analyzed. A positive control is located in a separate tube from the unknown samples, and its results apply to all the unknowns for the specific assay in the run. If amplification does not occur, then the control fails. This may be caused by PCR inhibitors contaminating the sample, or user error.

Negative control (NC): Does not contain the DNA target for which the unknown samples are being analyzed. A negative control is located in a separate tube from the unknown samples. A negative control applies to all the unknowns for the specified assay in the run. If amplification occurs, then the control fails. In this case, the sample is contaminated, and unknown samples may also be contaminated.

Inhibition Control (IC), Optional for Surveillance Runs: An inhibition control is a positive control to which unknown sample is added. Inhibition Controls are always paired with their unknown samples. Inhibition controls are considered a success if they amplify within a designated number of cycles of the Positive Control for the same assay and have signal increase greater than the designated range. The inhibition control is used to determine the presence of inhibitors, which might affect detection of target sequences. Any failed inhibition control will cause the correlated unknown to be called inhibited, and users will be instructed to consult a supervisor or the product insert. For further details about IC's, see Chapter 5 in this manual.

How Results are Displayed

When controls are used, the Qualitative Detection module displays three results for each sample: Control, Target, and Combined as described below:

Target result: The Target result is the call for the individual sample based on the sample's amplification profile.

Control result: The Control result displays the Success or Failure for the *combination* of all control replicates that apply to this sample. All the controls that apply to a particular example are treated together. If *any* of the control replicates fail, the Control column displays "Failure." Controls apply not just to Unknown samples, but also to other controls.

Combined result: The Combined result is based on the combination of the Control results and Target results for all replicates of the sample.

Possible Results for Target

Target result: The Target result is the call for the individual sample based on the specific capillary's amplification profile.

Positive	PC's, NC's, and samples	Individual capillary amplifies
Negative	PC's, NC's, and samples	Individual capillary fails to amplify
Uncertain	PC's, NC's, and samples	Amplification of individual capillary cannot be determined, perhaps because the Cp is not clearly defined or the amplification curve is inconsistent

Possible Results for Control

Control result: The Control result displays the Success or Failure for the *combination* of all control replicates that apply to this sample. All the controls that apply to a particular example are treated together. If *any* of the control replicates fail, the Control column displays "Failure." Controls apply not just to Unknown samples, but also to other controls. For example, if an analysis contains two Positive controls, each control applies to the other. Negative controls also apply to positive controls. A failure of one control causes a failure for the related controls.

The success or failure of a control affects whether a sample result is valid. In most cases, a control fails when it does not behave as expected. A control fails in the following circumstances:

- A **Negative Control** replicate shows amplification. In this case, samples may be contaminated or incorrectly placed in the carousel.
- A **Positive Control** replicate does not show amplification.
- An **Inhibition Control (optional in Surveillance)** can fail in three ways:
  - Any replicate does not show amplification.
  - Any replicate has a Cp that is later than the Positive Controls' Cp by a designated value
  - Any replicate has a final fluorescence below the acceptable range.

  A failed inhibition control means that the inhibition control and the unknown contain an inhibiting substance. Even if the Unknown sample is Positive, the control is considered failed. For details on Inhibition Controls see Chapter 5 of this manual.

Success	PC's and NC's	All Negative Control replicates for assay do not amplify And All Positive controls for the assay do amplify
	Samples	All Negative Control replicates for assay do not amplify And All Positive Control replicates for assay do amplify
Failure	PC's and NC's	Any Negative Control replicate for assay does amplify **Or** Any Positive Control replicate for assay does not amplify.
	Samples	Any Negative Control replicate for assay does amplify **Or** Any Positive Control replicate for assay does not amplify
	Empty	*For all*: No controls apply to this capillary

Possible Results for Combined

Combined result: The combined call for a sample is determined from the sample's target call (whether the sample shows amplification or not) and from the success or failure of controls that apply to the sample.

PC's and NC's	Success	All Negative Control replicates for assay do not amplify And All Positive Control replicates for assay do amplify
	Failure	Any Negative Control replicate for assay does amplify **Or** Any Positive Control replicate for assay does not amplify

For samples	Positive	If all controls succeed And If ***any*** of the sample replicates are Positive
	Negative	If all controls succeed And If the sample and ***all*** its replicates are Negative
	Uncertain	If all controls succeed And If ***any*** of the sample replicates are Uncertain
	Invalid	If either a Positive Template Control replicate or a Negative Template Control replicate fails, then the combined call is invalid for all samples for that assay.
	Inhibited	If the Positive Template Controls and the Negative Template Controls succeed, but an inhibition control for a sample fails, then the combined call for the associated sample(s) is inhibited.

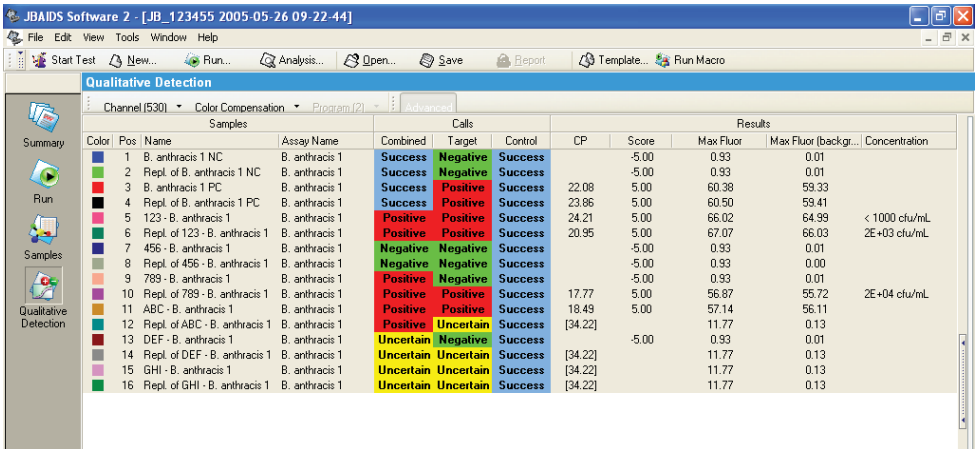
Click **Advanced** to display a **Results** section that includes the following (optional and available only to advanced operators):

Column Name	Description	Possible Values
Cp	The sample Cp, in cycles	A positive number with up to two decimal places
Score	A numerical value reflecting whether the target is positive, negative, or indeterminate Positive: A value greater than +1 Negative: A value less than -1 Uncertain: A value between +1 and -1 **Note:** The score does *not* indicate the confidence level of the call. For example, a score of 1.1 is no more or less positive than a score of 4.1.	A positive or negative number with up to two decimal places, or 0
Max Fluor	Highest level of fluorescence reached by sample	A positive number, with up to two decimal places
Max Fluor (Background)	Level of fluorescence increase, determined by subtracting baseline fluorescence level from highest level of fluorescence reached by sample	A positive number, with up to two decimal places

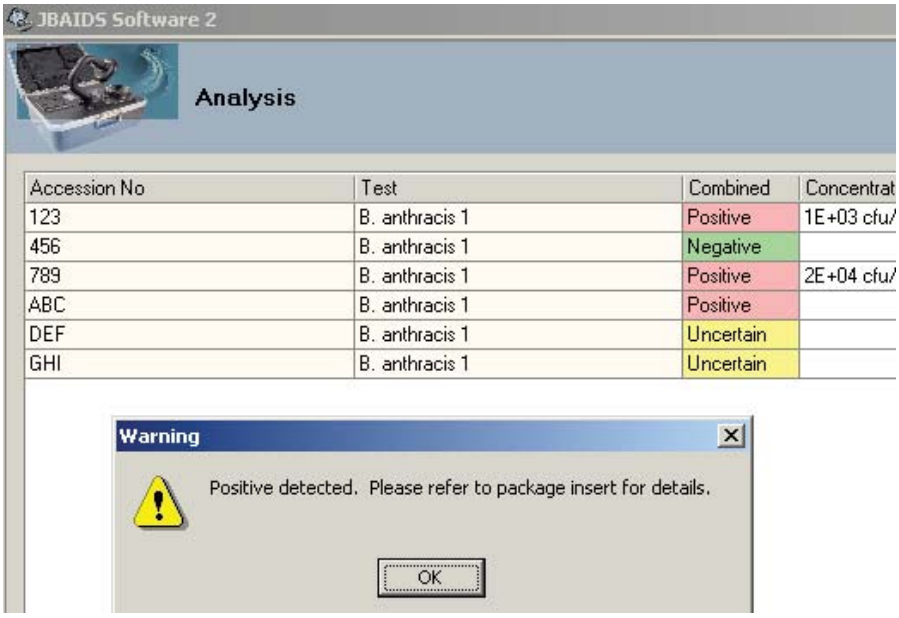
Concentration Reporting

In addition to the columns listed above, when an advanced operator is logged into the Qualitative Detection module, the software will report a concentration estimate (with units) for non-negative samples with the appropriate assay and specimen combinations. The software also provides the mean concentration of the replicates (with units) for all positive samples on the Wizard results screen. The JBAIDS software does not report a concentration for samples that have been called negative, invalid, uncertain, or inhibited, or that do not have the appropriate assay and specimen combinations. For example, the ABC sample in the Analysis Window below does not provide a concentration, because of its assay and specimen concentration. If the concentration value is below the limits of detection for the assay/specimen combination, the concentration will be given as “< x units” where x is the assay/specimen level of detection.

Concentration data is provided in the Qualitative Detection module

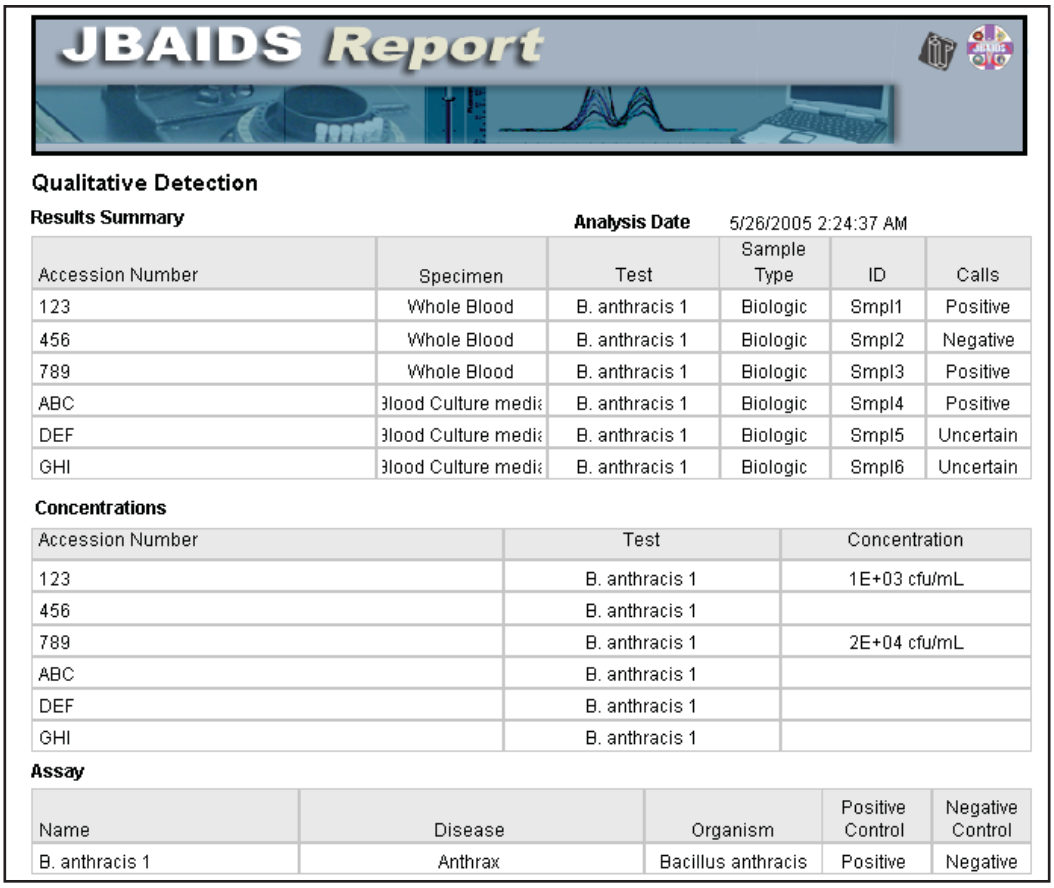

JBAIDS Software 2 - [JB_123455 2005-05-26 09-22-44]
File Edit View Tools Window Help
Start Test New... Run... Analysis... Open... Save Report Template... Run Macro
Qualitative Detection
Channel (530) Color Compensation Program (2) Advanced
Summary
Run
Samples
Qualitative Detection
Samples Calls Results
Color Pos Name Assay Name Combined Target Control CP Score Max Fluor Max Fluor (backgr... Concentration
1 B. anthracis 1 NC B. anthracis 1 Success Negative Success -5.00 0.93 0.01
2 Repl. of B. anthracis 1 NC B. anthracis 1 Success Negative Success -5.00 0.93 0.01
3 B. anthracis 1 PC B. anthracis 1 Success Positive Success 22.08 5.00 60.38 59.33
4 Repl. of B. anthracis 1 PC B. anthracis 1 Success Positive Success 23.86 5.00 60.50 59.41
5 123 - B. anthracis 1 B. anthracis 1 Positive Positive Success 24.21 5.00 66.02 64.99 < 1000 cfu/mL
6 Repl. of 123 - B. anthracis 1 B. anthracis 1 Positive Positive Success 20.95 5.00 67.07 66.03 2E+03 cfu/mL
7 456 - B. anthracis 1 B. anthracis 1 Negative Negative Success -5.00 0.93 0.01
8 Repl. of 456 - B. anthracis 1 B. anthracis 1 Negative Negative Success -5.00 0.93 0.00
9 789 - B. anthracis 1 B. anthracis 1 Positive Negative Success -5.00 0.93 0.01
10 Repl. of 789 - B. anthracis 1 B. anthracis 1 Positive Positive Success 17.77 5.00 56.87 55.72 2E+04 cfu/mL
11 ABC - B. anthracis 1 B. anthracis 1 Positive Positive Success 18.49 5.00 57.14 56.11
12 Repl. of ABC - B. anthracis 1 B. anthracis 1 Positive Uncertain Success [34.22] 11.77 0.13
13 DEF - B. anthracis 1 B. anthracis 1 Uncertain Negative Success -5.00 0.93 0.01
14 Repl. of DEF - B. anthracis 1 B. anthracis 1 Uncertain Uncertain Success [34.22] 11.77 0.13
15 GHI - B. anthracis 1 B. anthracis 1 Uncertain Uncertain Success [34.22] 11.77 0.13
16 Repl. of GHI - B. anthracis 1 B. anthracis 1 Uncertain Uncertain Success [34.22] 11.77 0.13

Analysis Window


JBAIDS Software 2
Analysis
Accession No Test Combined Concentrat
123 B. anthracis 1 Positive 1E+03 cfu/
456 B. anthracis 1 Negative
789 B. anthracis 1 Positive 2E+04 cfu/
ABC B. anthracis 1 Positive
DEF B. anthracis 1 Uncertain
GHI B. anthracis 1 Uncertain
Warning
Positive detected. Please refer to package insert for details.
OK

When an advanced operator is logged in, the mean concentrations (with units) of positive samples will be reported in the JBAIDS Report results section in a table that can be included in the printed report by selecting Concentrations from the report sections option. The table will include the sample accession number, the test name, the Detector call, and the concentration of positive samples. The default report will not include the mean concentrations. When a user is logged into the Diagnostic database, the software will not report concentration values on the report.

Concentration data is provided in the Wizard report



JBAIDS Report

Qualitative Detection

Results Summary **Analysis Date** 5/26/2005 2:24:37 AM

Accession Number	Specimen	Test	Sample Type	ID	Calls
123	Whole Blood	B. anthracis 1	Biologic	Smpl1	Positive
456	Whole Blood	B. anthracis 1	Biologic	Smpl2	Negative
789	Whole Blood	B. anthracis 1	Biologic	Smpl3	Positive
ABC	Blood Culture media	B. anthracis 1	Biologic	Smpl4	Positive
DEF	Blood Culture media	B. anthracis 1	Biologic	Smpl5	Uncertain
GHI	Blood Culture media	B. anthracis 1	Biologic	Smpl6	Uncertain

Concentrations

Accession Number	Test	Concentration
123	B. anthracis 1	1E+03 cfu/mL
456	B. anthracis 1	
789	B. anthracis 1	2E+04 cfu/mL
ABC	B. anthracis 1	
DEF	B. anthracis 1	
GHI	B. anthracis 1	

Assay

Name	Disease	Organism	Positive Control	Negative Control
B. anthracis 1	Anthrax	Bacillus anthracis	Positive	Negative

Summary of Results

Concentrations are only provided for agent/matrix combinations.

Control Results: Success for all capillaries.

- No Negative Control Replicates amplify **and**
- All Positive Control Replicates amplify

Combined Results:

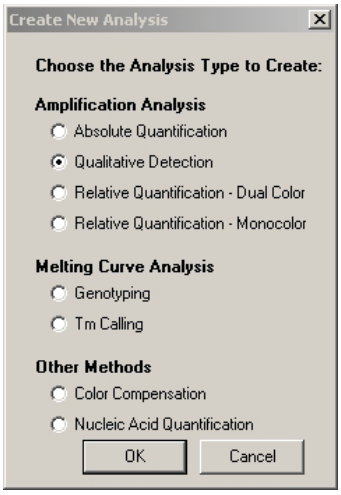
- 123 called positive because both replicates amplified (Target = Positive)
- 456 called negative because both replicates failed to amplify (Target = Negative)
- 789, called positive because one of the replicates amplified (Target = Positive)
- ABC, called positive because one of the replicates amplified (Target = Positive)
- DEF called uncertain because no replicates are positive and one replicate is uncertain
- GHI called uncertain because both replicates were called uncertain

Performing a Qualitative Detection Analysis on a Non-Wizard Run Using Controls

Follow the steps below to perform an analysis using any or all of the controls.

Note: The analysis must have completed at least 45 amplification cycles.

1. Open the analytical run you want to analyze.
2. Click **Analysis** on the global toolbar.
3. Select **Qualitative Detection,** then click **OK** in dialogue box.



When the dialog box opens with the question “Do you want to enter sample settings before creating the analysis,” select **Yes**. This will take you to the **Sample Module**.

Confirm
There are no sample settings for Absolute Quantification analyses.
Do you want to enter sample settings before creating the analysis?
Yes
No

4. In the **Sample Module** enter information about each sample in the **Capillary View** tab.
5. If this is a multicolor analytical run, in the **Sample data** toolbar, select the channels to be used in the analysis.
6. In the **Qual Detect** tab of the **Sample Data,** select **Enable Controls.**
7. Enter sample information for each channel (530, 640, or 705) in each row, as follows:

Column Name	Description	Options
Target Name	Name of the DNA target for this channel for this sample	Any name
Sample Type	The type of sample	Unknown Positive Control Negative Control Internal Control External (Inhibition) Control

Note: Internal Controls are specifically formulated reagents that contain two assays in each capillary. One of these is used as a indicator or “control” for PCR amplification. The JBAIDS reagents do not contain internal controls.

8. Again, click **Analysis** on the global toolbar and select **Qualitative Detection,** then click **OK** in dialogue box.
9. Select **Qualitative Detect** in the **module bar** to open the analysis module.
10. If this is a multicolor analysis:
    - From the **Channel** menu, select the channel you want to analyze.
    - To apply color compensation, click **Color Compensation,** then choose **Select Color Compensation.** Find and select the color compensation (.ccc) file for the instrument you are using.
11. From the **Program** menu, select an amplification program in the analytical run test (if there is only one amplification program, it is selected by default).
12. View the results for each sample in the **Combined, Target,** and **Control** columns of the **Calls** section.

13. (Optional) Click **Advanced** to display a **Results** section that includes the following:

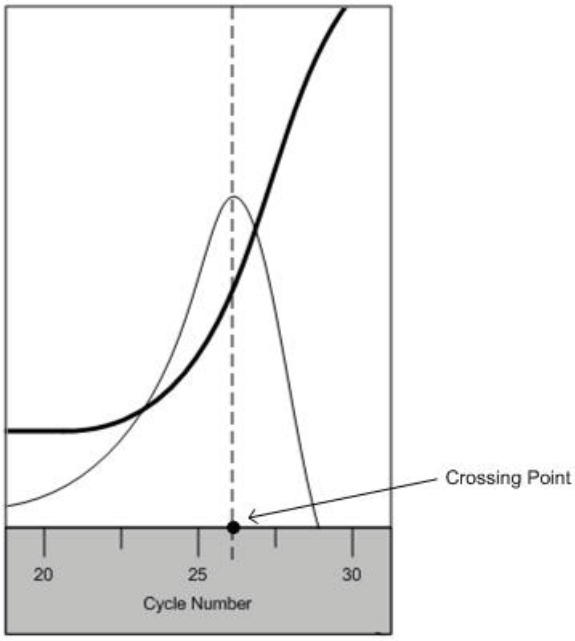
Column Name	Description	Possible Values
Cp	The sample Cp, in cycles	A positive number with up to two decimal places
Score	A numerical value reflecting whether the target is positive, negative, or indeterminate **Positive**: A value greater than +1 **Negative**: A value less than -1 **Uncertain**: A value between +1 and -1 **Note:** The score does *not* indicate the confidence level of the call. For example, a score of 1.1 is no more or less positive than a score of 4.1.	A positive or negative number with up to two decimal places, or 0
Max Fluor	Highest level of fluorescence reached by sample	A positive number, with up to two decimal places
Max Fluor (Background)	Level of fluorescence increase, determined by subtracting baseline fluorescence level from highest level of fluorescence reached by sample	A positive number, with up to two decimal places
Concentration	Estimated amount of template present in sample	A positive number, with appropriate units. If the value is below the limits of detection, the concentration will be given as “< x units” where x is the assay/ specimen limit of detection.

PERFORMING ABSOLUTE QUANTIFICATION ANALYSIS

An Absolute Quantification analysis determines the concentration of target DNA in unknown samples.

Understanding the Automated Method

The Automated method identifies the Cp of a sample as the maximum of the second derivative of the sample's fluorescence curve, which corresponds to the point where the sample's fluorescence curve turns sharply upward.



The Automated method requires little input. You must determine how to provide the Standard Curve for the run; the software handles all other analysis calculations.

The software automatically copes with effects and artifacts such as spikes in the log-linear phase of the curve, noisy plateaus, or curves where the plateau phase has not yet been reached. Additionally, no Cp values are displayed for curves with a slowly increasing, decreasing, or noisy background, unless the curves reach considerable values of fluorescence compared to the background.

Using the Automated Method with Controls

If you use the automated method, you can include negative and positive controls in the quantification analysis to help ensure that samples have not been contaminated and that the reaction is performing as it should.

How a negative control is used

A negative control does not contain the target DNA sequence and should show no amplification (have no Cp). It is located in a separate tube from the unknown samples. The control is considered a success if the results of all replicates are negative and a failure if the results of any replicates are positive.

How a positive control is used

A positive control contains a known concentration of the target DNA sequence. It is located in a separate tube from the unknown samples. The positive control should show amplification characteristic of the target DNA sequence.

You can specify the concentration range expected for the positive control. In this case, the unknown samples can be called positive or negative *only if* the positive control's calculated concentration falls within its expected range.

Specifying a concentration range helps to ensure that the correct Standard Curve has been applied to the analysis. If the analysis results show that the positive control's calculated concentration is outside its expected range, then the wrong Standard Curve may have been applied to the analysis or the standards may not be behaving as expected.

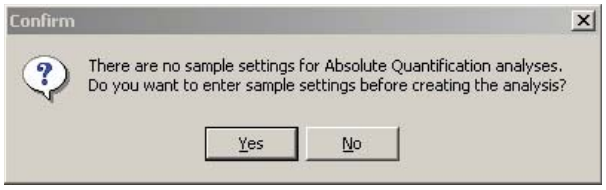
Performing the Analysis Using Controls and In-Run Standards in the Analytical Run

IMPORTANT: The analysis must have at least 11 amplification cycles and at least one sample of known concentration (standard).

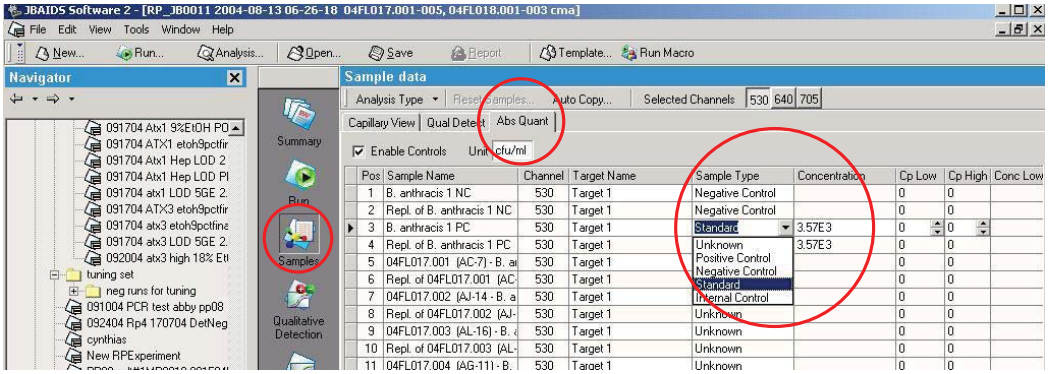
To perform an Automated analysis using controls and in run standards

1. Open the desired Analytical Run.
2. Click **Analysis** on the main toolbar.
3. Select **Absolute Quantification** then click **OK**.

When the dialog box opens with the question, "Do you want to enter sample settings before creating the analysis," select **Yes**. This will take you to the **Sample Module**.


Confirm
There are no sample settings for Absolute Quantification analyses.
Do you want to enter sample settings before creating the analysis?
Yes
No

4. Select the **Capillary View** Tab. Ensure that all information for the sample is correctly entered, including name, replicate, ID, and assay (target).
   Select the **AbsQuant** tab. Check the **Enable Controls** box. Select the appropriate channels you wish to analyze. For each sample enter the correct sample type (Negative Control, Positive Control, Unknown, or Standard).


JBAIDS Software 2 - [RP_JB0011 2004-08-13 06-26-18 04FL017.001-005, 04FL018.001-003 cma]
File Edit View Tools Window Help
New... Run... Analysis... Open... Save Report Template... Run Macro
Navigator
Sample data
Analysis Type
Auto Copy...
Selected Channels 530 640 705
Capillary View Qual Detect Abs Quant
Enable Controls
Summary
Run
Samples
Qualitative Detection
Pos Sample Name Channel Target Name Sample Type Concentration Cp Low Cp High Conc Low
1 B. anthracis 1 NC 530 Target 1 Negative Control
2 Repl. of B. anthracis 1 NC 530 Target 1 Negative Control
3 B. anthracis 1 PC 530 Target 1 Standard 3.57E3
4 Repl. of B. anthracis 1 PC 530 Target 1 Unknown 3.57E3
Positive Control
Negative Control
Standard
Internal Control
tuning set
neg runs for tuning
091004 PCR test abby pp08
092404 Rp4 170704 DetNeg
cynthias
New RPExperiment

For standard samples enter the known concentration. This analysis requires at least two standards.

5. Again, click **Analysis** on the global toolbar and select **Absolute Quantification,** then click **OK** in dialogue box.
6. Select **Absolute Quantification** in the **module bar** to open the analysis module.
7. A quantification analysis is performed and displayed in the work pane of the window.

   If this is a multicolor analysis:

   - From the **Channel** menu, select the channel you want to analyze.
   - To apply color compensation, click **Color Compensation,** then choose **Select Color Compensation.** Find and select the color compensation (.ccc) file for the instrument you are using.
8. To view analysis results, click and drag the left border of the chart section to the right to display all the result data.

   In addition to the results for a standard Automated analysis, a Calls section is added to the results. For more information about these results see the Qualitative Detection Analysis section in this chapter.

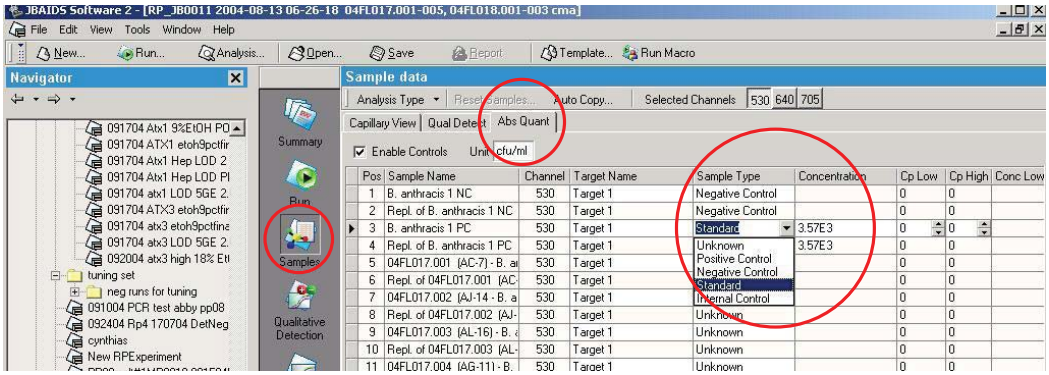
Performing the Analysis Using Controls and External Standards in the Analytical Run

1. Open the analytical file you wish to add the standard curve to in the work pane, click on the **Analysis** button on the tool bar at the top of the screen. The **Create New Analysis** appears.

   Select **Absolute Quantification** and click **OK**. Enter sample settings if necessary.

   If you are not prompted to enter sample settings, then select the **Sample module** icon and click on the **Abs Quant** tab.

   In the sample data window, make sure that one sample is labeled **Standard** and that the **Concentration** for that sample is specified. This is required in order to correlate curves in this run with the Standard Curve. After editing the Sample Data, select the **Absolute Quantification** icon in the module pane, (it may be necessary to select **Analysis**, **Absolute Quantification** as discussed in Step 4 if the icon does not appear in the module pane).

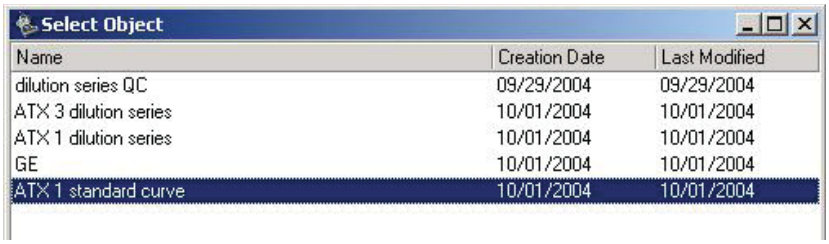

JBAIDS Software 2 - [RP_JB0011 2004-08-13 06-26-18 04FL017.001-005, 04FL018.001-003 cma]
File Edit View Tools Window Help
New... Run... Analysis... Open... Save Report Template... Run Macro
Navigator
Sample data
Analysis Type Reset Samples... Auto Copy... Selected Channels 530 640 705
Capillary View Qual Detect Abs Quant
Enable Controls Units cfu/ml
Summary
Run
Samples
Qualitative Detection
Pos Sample Name Channel Target Name Sample Type Concentration Cp Low Cp High Conc Low
1 B. anthracis 1 NC 530 Target 1 Negative Control
2 Repl. of B. anthracis 1 NC 530 Target 1 Negative Control
3 B. anthracis 1 PC 530 Target 1 Standard 3.57E3
4 Repl. of B. anthracis 1 PC 530 Target 1 Unknown 3.57E3
Positive Control
Negative Control
Standard
Internal Control
Unknown

2. For standard curve analysis, you will need to obtain a Standard Curve file. You may already have a Standard Curve file loaded into your software. This can be verified by looking in the Special Data/Std Curve directory under your user folder in the Navigator pane.

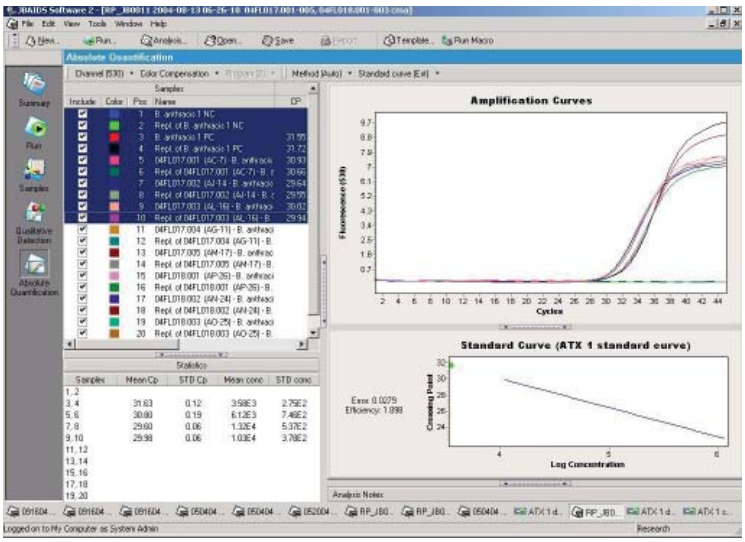
   If you do not have any Standard Curve files in your navigator pane or would like to import a Standard Curve file that is unique to the reagents and extraction method, import a file from the current location and save it in the **Special Data/Std Curve** folder.

3. On the Absolute Quantification toolbar, use the **Standard Curve** drop down menu and select **Use external**.

4. The Select Object window opens with a list of the available Standard Curves. Select the desired **Standard Curve** and click **OK**. If you do not see the desired Standard Curve, repeat steps 2–4 above.



8. The Standard Curve for this analysis is now shown in the bottom right pane, and concentration data is now displayed for each curve in the Samples pane under the Concentration column. In addition, the Statistics Section contains averages and standard deviations for concentrations and Cps of replicates.



Saving a Standard Curve for External Use

1. Open an analytical run with an Absolute Quantification module that contains a standard curve.
2. Under the **Standard Curve** drop-down menu, select **Save as external...**
3. Save the file to the **Special Data/Std Curve** folder.

USING MELTING PROFILES TO IDENTIFY DNA PRODUCTS

Note: Melting profiles can be performed on Hybridization probes, SimpleProbes™ and double-strand binding dyes.

The temperature at which a DNA strand separates or *melts* when heated can vary over a wide range, depending on the sequence, the length of the strand, and the GC content of the strand. For example, the melting temperature (or Tm) can vary for products of the same length but different GC/AT ratio, or for products with the same length and GC content, but with a different GC distribution. Even single-base differences in heterozygous DNA can result in melting temperature shifts.

Melting temperature analysis can be used to identify and genotype DNA products and to identify unwanted by-products. It can also be used to detect mutations, because a probe that hybridizes over a sequence variant melts at a lower temperature. Thus the melting temperature shift (ΔTm) between a normal allele-probe match and a mutated allele-probe mismatch indicates the presence of the mutation.

To analyze melting temperature profiles, the fluorescence of the samples must be monitored while the JBAIDS instrument temperature is steadily increased. As the temperature increases, sample fluorescence decreases. In the specific case of hybridization probes, this is due to the separation of target-probe hybrids resulting in the spatial separation of the dye molecules and a consequent drop in fluorescence.

How Data is Displayed in a Melting Temperature Analysis

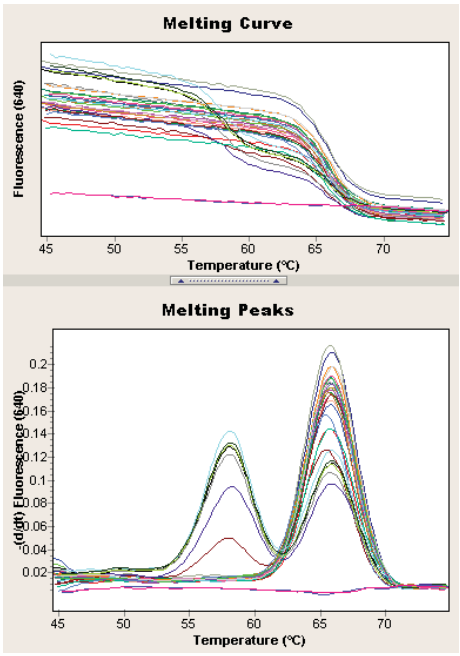
A melting temperature analysis can be performed on any analysis that includes a melt program (a program in which temperature is steadily increased as fluorescence is monitored).

A melting temperature analysis uses the fluorescence measurements of the melt program to determine the Tm of each sample. The Tm of a sample is defined as the point at which half the probes (or dyes) have melted off the DNA.

The analysis includes a melting curve chart that plots sample fluorescence vs. temperature. The chart displays characteristic downward curves as sample fluorescence decreases.

The analysis also includes a chart that plots the negative derivative [(-d/dT) • Fluorescence] of the sample fluorescence curves. In this chart, the melting temperature of each sample appears as a peak. The area under the melt peak corresponds to the amount of product with a particular melting temperature. Displaying the melting temperature as a peak makes it easier to distinguish each sample's characteristic melting profile and to discern differences between samples.

The following figure illustrates a melting curve chart and a melting peak chart.



In the melting peak chart, some sample curves include two peaks. These curves indicate heterozygous samples. After DNA amplification, a heterozygous sample contains two DNA sequences, which each melt at a different temperature, producing a characteristic two-peak curve for the sample.

Types of Melting Temperature Analysis

The JBAIDS software includes two types of melting temperature analysis:

- The **Genotyping** analysis groups together samples with similar melting profiles and identifies each group as a genotype. You can import melting curves for known genotypes and apply them to the samples, or you can include melting standards in the analysis.
- The **Tm Calling** analysis calculates the melting temperature and the melting peak data for each sample. Use the Tm calling analysis to identify characteristic melting profiles of DNA products.

JBAIDS SOFTWARE TOOLS

The JBAIDS software includes the following tools and commands

- A query tool used to find items in the database; for more information, see “Using queries to find information,” below.
- Instrument and application diagnostic tools, including an instrument self-test, error and operation logs, and an application error log; for more information, see “Using self-diagnostic tools,” below.
- A chart preferences dialog box used to specify the look and feel of charts displayed in the run and analysis software; for more information, see “Setting chart preferences,” below.

Using Queries to Find Information

The JBAIDS software includes a query tool you can use to search for and retrieve analytical runs and other items stored in the software database.

To create and execute a query

1. Click **New,** select the **Query** icon, then click **OK.**
2. In the **Object Type** box, select the type of item to look for, such as Analytical Run.
3. (Optional) Enter the **Name** of the item to search for or the **Owner** of the item, if known.
4. Select **Modified Date** or **Creation Date** to specify which type of date you want to use in the query.
5. Select a date range.
6. You can specify the number of months or days before the current date to search, or you can select a beginning and ending date.
7. To refine the search, click **Advanced,** then enter additional search criteria. The available search options depend on the type of item you are looking for.
8. Click **Search.** Results are displayed to the right of the search criteria. The results include the following:
   - Item name
   - Item type
   - Date the item was created
   - Date the item was last modified

Note: If an error message is displayed stating that the query engine needs to be updated, you must update the database (see “Updating the Database,” later in this section).

9. To open an item, double-click the item name.
10. To save the query, in order to search the database later with the same parameters, click **Save.**
11. A file list opens. Select a location, (the default location for saved queries is in the Query folder under the Special Data folder for your user account) enter a query name, and then click **OK.**
12. To close the search window, click **Close.**

To execute a saved query

1. Find the query you want in the **Navigator.** The default location for saved queries is in the Query folder under the Special Data folder for your user account.
2. Double-click the query name to open the query in the Query window.
3. In the **Query** window, click **Search** to execute the query.

Updating the Database

If your user account is assigned the advanced operator role, follow the steps below to update the database. Otherwise, see your system administrator.

Prerequisites

- You must have advanced operator privileges to update the database.
- There must be no other users using the database.

To update the database

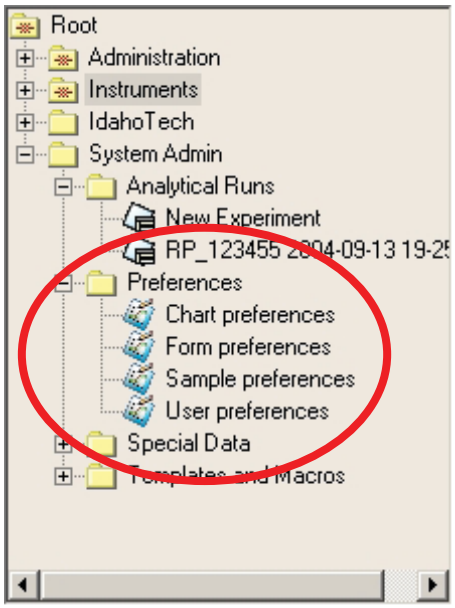
1. From the **Tools** menu, select **Database Status.**
2. Check the list of users in the **Logged In Users** tab. If other users are logged in, you cannot update the database. (The buttons on the Query Engine tab are inactive.)
3. If no other users are logged in, select the **Query Engine** tab.
4. Click **Update.** You are reminded that the update will take several minutes.
5. Click **Yes** to clear the message and continue. After the database is updated, a message states that the update is complete.
6. Click **OK** to clear the message. The Query Engine tab states that the query engine is now up to date.
7. Close the **Database Status** dialog box.

SOFTWARE PREFERENCES

The JBAIDS software provides the following *preferences* you can use to customize charts and samples and to set various default options:

- **Chart preferences:** determines the default appearance and content of your charts.
- **Sample preferences:** determines the default sample names in the **Sample Module** and the default colors and line styles of samples in charts.
- **User preferences:** determines default import and export directories and other settings.

Each set of preferences is stored as a separate item under your user folder in the JBAIDS software Navigator. When you open a preferences item, a window opens in the work pane where you can set the preference options.



You can have multiple Chart, Sample, and Form preference items, each with different settings. You can then choose the one you want to specify as the default.

If all the preference items of a particular type, such as chart, are deleted, the JBAIDS software creates a new default preferences item when you log in.

This section explains how to

- Use each type of preference
- Create multiple instances of preference items and specify an instance as the default for that preference type

Using Chart Preferences

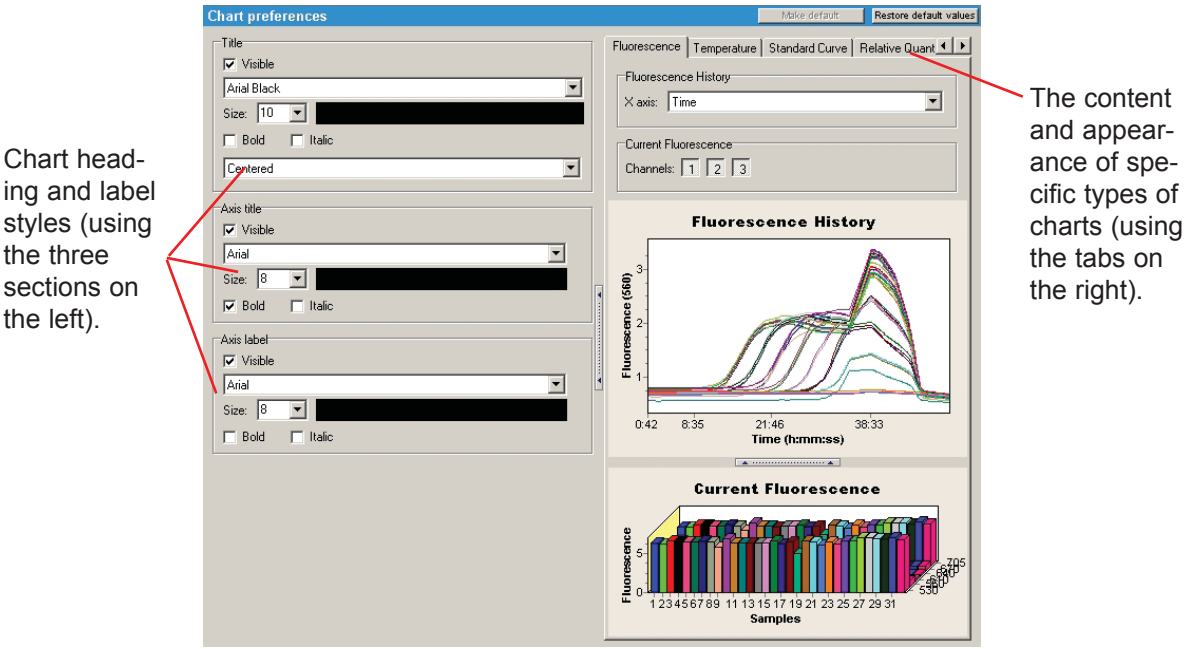
By default, your user account includes an item called *chart preferences* that determines the default appearance and content of your charts. You can change the default chart settings as needed.

You can also save a modified version of a chart preferences item with a new name and then apply the preferences in place of the defaults. You can have as many different chart preferences items as you want, each one defining a different look and feel for your charts. For more information, see “Creating a Separate Preferences Item and Making It the Default” in this chapter.

You can override the current chart preferences for individual charts, analyses, or analytical runs. See “Overriding Default Chart Preferences” in this chapter.

To open the chart preferences item

1. In your **Navigator** user folder**,** open the **Preferences** subfolder.
2. Double-click **Chart preferences.** Using the Chart preferences window, you can customize the following chart settings:



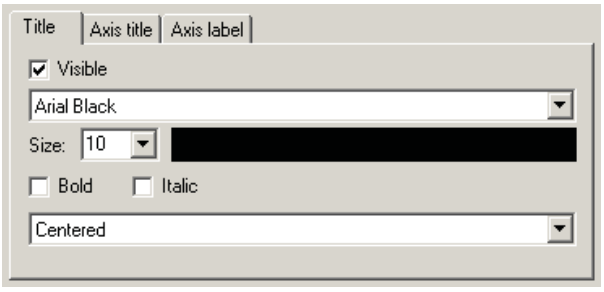
Specifying Chart Heading and Label Styles

Use the following three boxes on the left of the window to modify headings and labels:

Title: Specifies the appearance of chart titles.
Axis title: Specifies the appearance of the text below the X-axis and to the left of the Y-axis on the charts.
Axis label: Specifies the appearance of the measurement values on an axis, such as time on the X-axis of a Fluorescence chart.
Each of the three sections has the same format options, except that the Title section includes an option for title position.

To specify heading and label styles

1. In the appropriate section, select or deselect the **Visible** check box to include or exclude this type of text on charts.



2. Specify the text appearance as follows:
   - Select the typeface from the pull-down list in the first box.
   - Select the type size from the pull-down list in the Size box or enter a value.

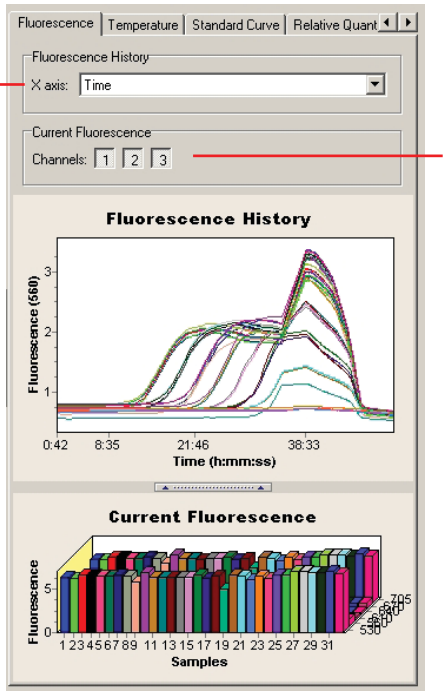
- To change the text color, click the colored bar to the right of the Size box to display a color palette. Select the color you want, then click OK.
- To make the text bold or italic, select the Bold or Italic check box (or both).
- (Title only) To position the chart title, select a position from the pull-down list in the last box.

3. Click **Save** in the global toolbar to save your settings.

Specifying the Content of Fluorescence Charts

The Fluorescence tab of the Chart Preferences window controls the default appearance of the fluorescence data displayed in these two fluorescence charts:

The default axis value for the Fluorescence History chart that graphs fluorescence vs. time, cycles, or temperature



The default channels for the Current Fluorescence bar chart that displays the level of fluorescence for each sample in each channel at a particular acquisition point

Fluorescence charts are displayed on both the Online Data Display tab of the **Run** module and on the Raw Data tab of the **Summary** module.

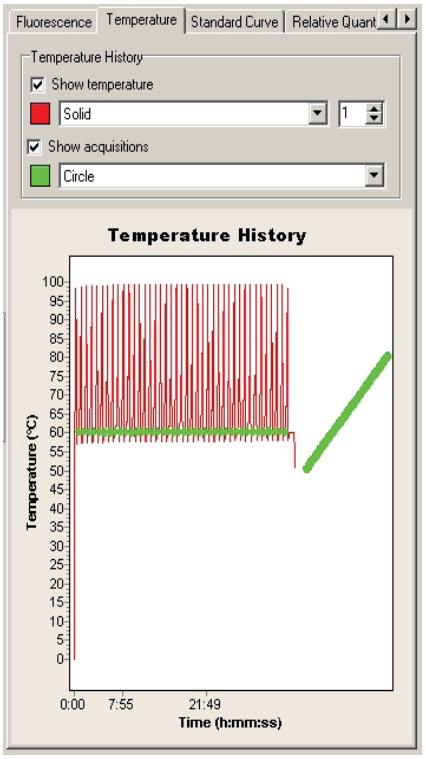
To specify fluorescence chart information

1. Select the **Fluorescence** tab (if not already selected).
2. In the **Fluorescence History** box, select a value for the X-axis from the pull-down list.
3. In the **Current Fluorescence** box, click each channel you want to include in the Current Fluorescence bar chart.
4. Click **Save** in the global toolbar to save your settings.

Specifying the Content and Appearance of the Temperature Chart

The Temperature tab of the Chart Preferences window controls the appearance of the Temperature History chart, which displays temperature readings and fluorescence acquisition points.

To specify content and appearance of the Temperature chart

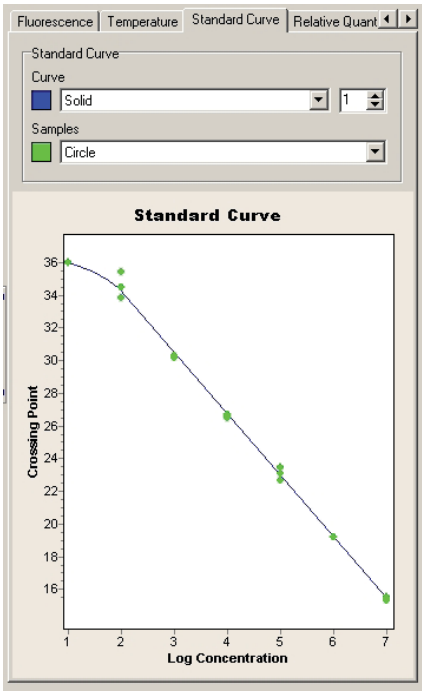


1. Select the **Temperature** tab.
2. To include or exclude temperature readings, select or deselect the **Show temperature** box.
3. To specify the appearance of the temperature lines on the chart:
   - To specify line color, click the colored box under **Show temperature** to display a color palette, select the color you want, then click **OK.**
   - To specify line style, select a style from the pull-down list.
   - To specify the line width, enter or select a value.
4. To include or exclude all fluorescence acquisition points, select or deselect the **Show acquisitions** box.
5. To specify the appearance of the acquisition points:
   - To specify point color, click the colored box under **Show acquisitions** to display a color palette, select the color you want, then click **OK.**
   - To specify a point style, select a style from the pull-down list.
6. Click **Save** in the global toolbar to save your settings.

Specifying the Appearance of Standard Curve Charts

The Standard Curve tab of the Chart Preferences window controls the appearance of the Standard Curve charts in quantification analyses.

To specify the appearance of the standard curve and sample points

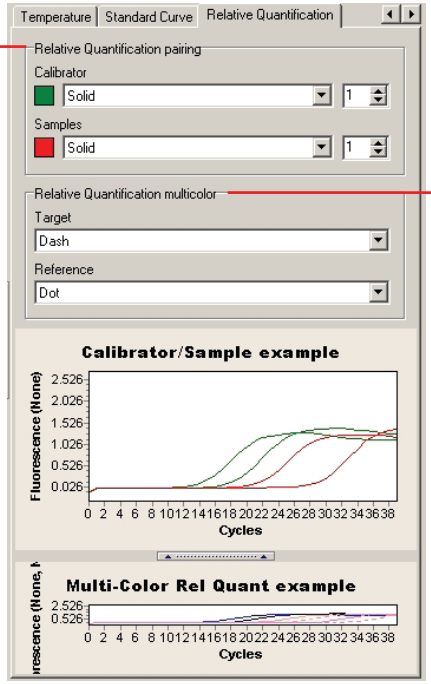


1. Select the **Standard Curve** tab.
2. To specify the appearance of the curve:
   - To specify line color, click the colored box under **Curve** to display a color palette, select the color you want, then click **OK.**
   - To specify line style, select a style from the pull-down list.
   - To specify line width, enter or select a value.
3. To specify the appearance of the sample points:
   - To specify point color, click the colored box under **Samples** to display a color palette, select the color you want, then click **OK.**
   - To specify point style, select a style from the pull-down list.
4. Click **Save** in the global toolbar to save your settings.

Specifying the Appearance of Relative Quantification Charts

The Relative Quantification tab of the Chart preferences window controls the appearance of Relative Quantification pairing charts and multicolor Relative Quantification charts.

The Pairing chart displays amplification curves for target and reference unknowns and for target and reference calibrators. The curves for the unknowns have a different appearance than the curves for the calibrators. You can customize these settings.



The charts in a multicolor Relative Quantification analysis display amplification curves for target and reference samples that are in the same capillary tube. These samples have the same sample name and sample color and therefore must be distinguished by different line styles. You can customize these settings.

To specify the appearance of the Relative Quantification charts

1. Select the **Relative Quantification** tab.
2. To specify the appearance of the Calibrators in the pairing chart:
   - To specify line color, click the colored box under **Calibrator** to display a color palette, select the color you want, then click **OK.**
   - To specify line style, select a style from the pull-down list.
   - To specify the line width, enter or select a value.
3. To specify the appearance of the **Samples** (the unknowns) in the pairing chart:
   - To specify line color, click the colored box under **Samples** to display a color palette, select the color you want, then click **OK.**
   - To specify line style, select a style from the pull-down list.
   - To specify the line width, enter or select a value.

Note: Make the appearance of calibrators and samples different enough so that you can easily distinguish them. Refer to the sample chart to view your choices.

4. Specify the line styles of references and targets in the multicolor charts as follows:
   - Under **Target**, select a line style for targets from the pull-down list.
   - Under **Reference,** select a line style for references that is different from the Target style. Refer to the sample chart to view your choices.
5. Click **Save** in the global toolbar to save your settings.

Overriding Default Chart Preferences

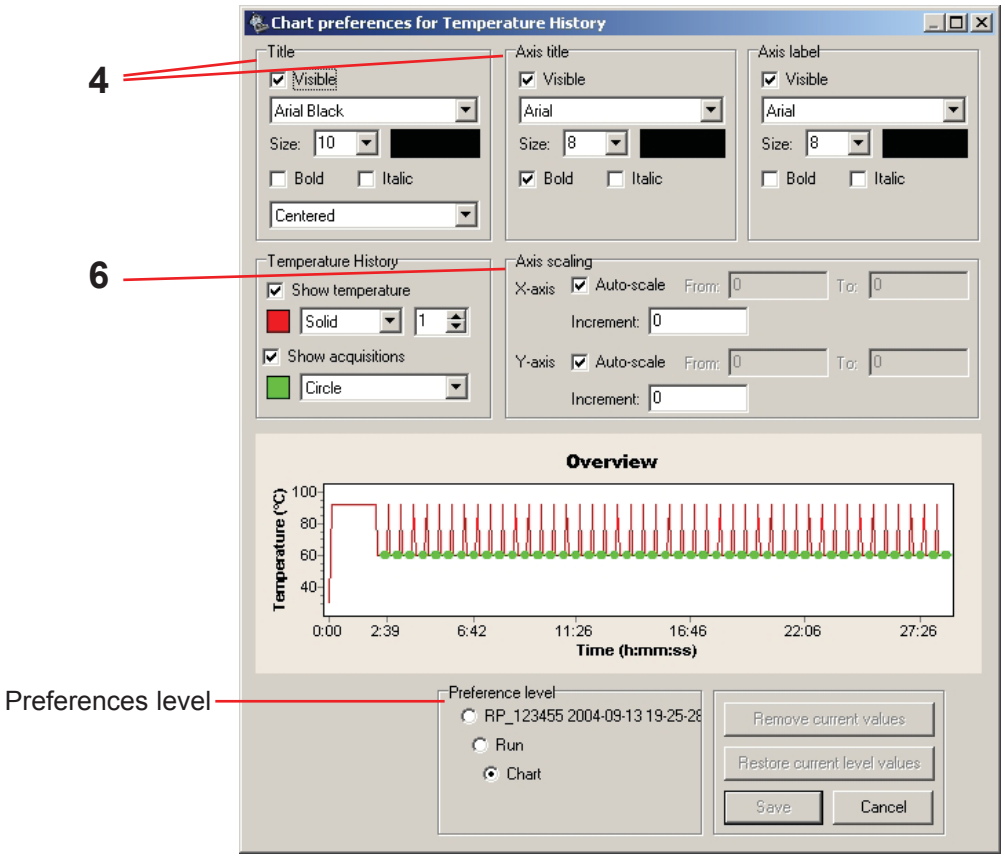
In some cases, you may want an individual chart, analysis, or analytical run to use different chart settings from the defaults you specified in the Chart Preferences item. You can override the default settings at the following levels:

- An individual chart
- All charts within an analysis
- All charts within a run

When you specify custom settings at any of these three levels, the new settings take precedence over the default values for the charts at that level.

To override chart preferences

1. Right-click the chart you want to modify.
   Or
   To override preferences for all charts within an analysis or within the analytical run, right-click any chart in the test.
2. Select **Chart Preferences**.



A Chart Preferences dialog box opens that contains options for the chart type similar to those in the Chart Preferences window, described above. However, the dialog box includes additional options for setting the chart X and Y-axis scales.

Before you make any changes, you must select the level at which to apply the changes.

3. In the **Preferences level** area, select one of the following:
   - Select the test name to apply the settings to all charts in the current run.
   - Select the analysis name to apply the settings to all charts in the current analysis. (You must have opened the menu from an analysis chart for this option to be available.)
   - Select Chart to apply the settings only to the current chart.
4. Change text settings in the Title, Axis title, and Axis label boxes, as needed.

   For more information, see “Specifying chart text,” above.
5. Change the chart-specific settings (if any) in the box below the Title section.

   The options displayed depend on the type of chart that was active when you opened the dialog box. For some chart types, there are no chart-specific settings.
6. In the Axis scaling area, set the range of units for the X-axis and Y-axis and the increment size.

   If you select 0 as the increment size, the increment size is determined automatically. If you set an increment size so small that the labels overlap, the setting is ignored and the increment size is determined automatically.
7. If you need to undo your changes and restore the previous values for the selected level, click **Remove current values.**
8. When finished, click **Save**.

Using Sample Preferences

You can modify the appearance of sample lines and points on charts in two ways:

- By modifying the sample preferences that apply to all runs. You can modify the default sample preferences item or create multiple versions of the default item and apply the version you want.
- By overriding the sample preferences for the current run. You can override preferences for multiple samples in the run or for an individual sample on a chart.

Note: You cannot change sample names for an existing run.

Modifying the Sample Preferences for All Analytical Runs

By default, your user account includes an item called *sample preferences* that determines the default sample names and the appearance of sample lines and points on all JBAIDS software charts. You can change the settings in the sample preferences item as needed. You can also save multiple versions of the sample preferences item and then apply the preferences you want.

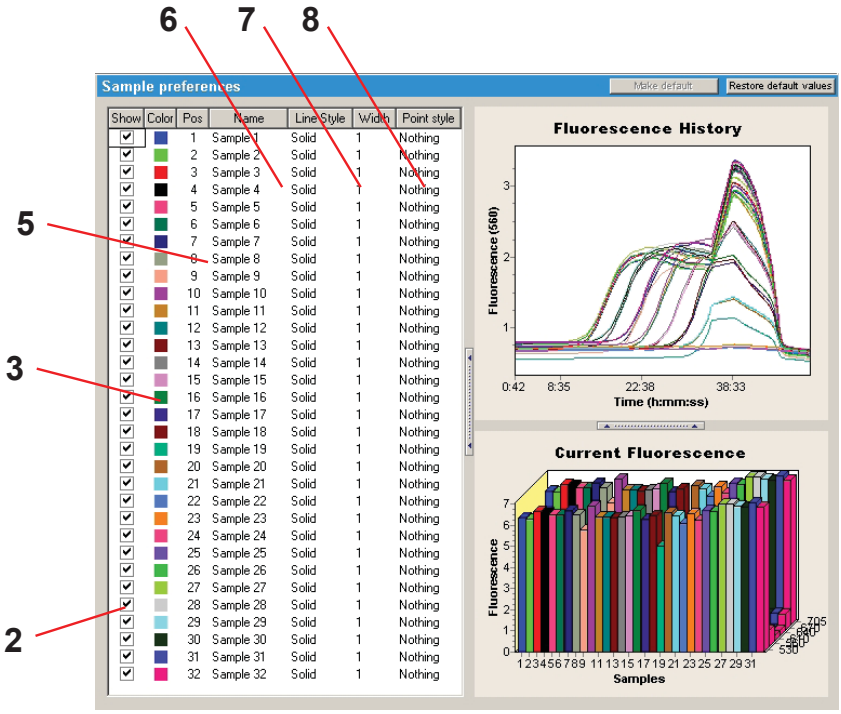
To modify default sample preferences

As you follow steps 3–8 below, remember that you can change settings for a contiguous group of samples at one time. To change settings for a group:

- Select the item you want to change for the first sample in the group.
- Hold down the **Shift** key**,** then select the same item for the last sample in the group.
- Press **F2.**
- Change the value for the first sample.

The changes are applied to all the selected samples.

1. In your **Navigator** user folder**,** open the **Preferences** subfolder, then double-click **Sample preferences.**



1. To include or exclude a sample in charts, select or deselect the sample's check box.
2. To change a sample's default color, click the colored square next to the sample name in the sample list to open a color palette.
3. Select the color you want, and then click **OK.**
4. The sample color appears next to the sample name in the JBAIDS software analytical run results and is used for sample lines and points in the charts.
5. To change the default sample name, click the sample name, then type a new name.
6. The default sample name is applied to new analytical runs; existing runs are not affected.
7. To change the line style used for the sample, click in the **Line Style** column, then select a new style from the pull-down list.
8. For example, you can select a dashed line instead of a solid line.
9. To change the line width, click in the **Width** column, then enter a new width.
10. If you prefer to see a sample line as a string of measurement points, click in the **Point Style** column, then select a style from the pull-down list. (If you prefer solid lines, leave the **Point Style** set to "Nothing.")
11. Click **Save** in the global toolbar to save your settings.

To create a separate preferences item and make it the default

1. In your **Navigator** user folder**,** open the **Preferences** subfolder, then double-click **Sample preferences.**
2. Modify the preferences, as needed. For more information, see “To modify default sample preferences,” above.
3. From the **File** menu, select **Save As.**
4. Navigate to a location to save the item, enter a name for the new preference item, then click **Save.**
5. To make this sample preferences item the default, click **Make Default** in the preferences title bar.

Note: You can also specify the default sample preferences item using an option in the User Preferences. For more information, see “Specifying User Preferences,” below.

Overriding Default Sample Preferences

At times you may want to change the appearance of samples in just one analytical run or chart, without changing the defaults applied to all analytical runs. Or you may want to change settings for a chart and then save the settings as a sample preferences item that can be applied to other analytical runs.

At the analytical run level, you can so the following

- Use a sample preference editor to change the appearance of multiple samples in the analytical run.
- Apply an existing sample preferences item to the run.
- Change the appearance of an individual sample line.
- Save analytical run settings as a sample preferences item.
- Clear any changes and reapply the default sample preferences.

Note: You cannot change the sample names or positions in an existing analytical run.

To use the preference editor to change multiple samples

1. Open the analytical run for which you want to modify the samples.
2. Right-click the chart that contains sample information.
3. Select **Sample Preferences.**
4. Modify the settings, then click **Save.** Modify the settings as you would if you were modifying the default sample preferences item. For more information, see “To modify default sample preferences,” above.
5. Click **Save** in the global toolbar to save the analytical run with the new settings.
6. Your settings are applied to all the charts in the current analytical run, but do not affect other runs or the default sample preferences settings. The settings are saved with the analytical run.

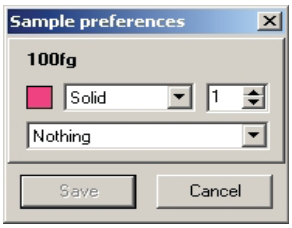
To apply a sample preference item to an analytical run

The sample preferences in a sample preferences item can be applied to individual analytical runs.

1. Open the analytical run for which you want to modify the samples.
2. Right-click any of the charts that contains sample information.
3. Select **Load Sample Preferences.**
4. Select the sample preferences item from the navigator, then click Open.

   The settings are applied to all charts in the analytical run.
6. Click **Save** on the global toolbar to save the analytical run with the new settings.

To modify an individual sample line



1. Open the analytical run for which you want to modify the sample line.

   Make sure a chart is displayed that contains the line you want to change. In an analytical run module, select the sample in the sample list to display its line in an analysis chart.
2. Move the mouse pointer over the line until the pointer changes to a hand, then left click the line.
3. A small dialog box opens containing settings for the line.
4. To change the line color:
   - Click the colored box to open a color palette.
   - Select a new color, then click OK.
5. To modify the line style, width, and measurement symbol, select the values from the pull-down lists.
6. Click **Save.**

   The line is changed in all charts in the current analytical run.
7. Click **Save** in the global toolbar to save the changes with the analytical run.

To save analytical run settings as a sample preferences item

1. Open the analytical run that has the settings you want to save as a sample preferences item.
2. Right-click a chart that contains sample information.
3. Select **Save Sample Preferences.**
4. Navigate to a location to save the sample preferences item, type a name for the item, then click **Save.**

To reapply default sample preferences

1. Open the analytical run for which you want to reapply the default sample preferences.
2. Right-click any of the charts that contains sample information.
3. Select **Clear Sample Preferences.**

   The samples in the charts are reset to the current default sample preferences.
4. Click **Save** in the global toolbar to save the analytical run with the settings.

Creating a Separate Preferences Item and Making it the Default

You can create multiple chart or sample preference items and then specify which item is to be used as the default. You can change the default designation whenever needed.

If you delete all instances of a preference item, such as all chart preference items, the software creates a new default item the next time you login. The settings are the application defaults.

To create a separate preference item and specify it as the default.

1. In your **Navigator** user folder**,** open the **Preferences** subfolder, then double-click the default item for the preference type you want (**Sample preferences** or **Chart preferences**).
2. Modify the preferences, as described in the previous procedures.
3. From the **File** menu, select **Save As.**
4. Navigate to a location to save the new preference item, type a name for the item, then click **Save.**
5. To make this item the default, click **Make Default** in the preferences title bar. The new default settings are applied immediately and will be applied as the default preferences the next time you login.

Note: You can also specify the default preference items using options in User Preferences. For more information, see “Specifying User Preferences,” below.

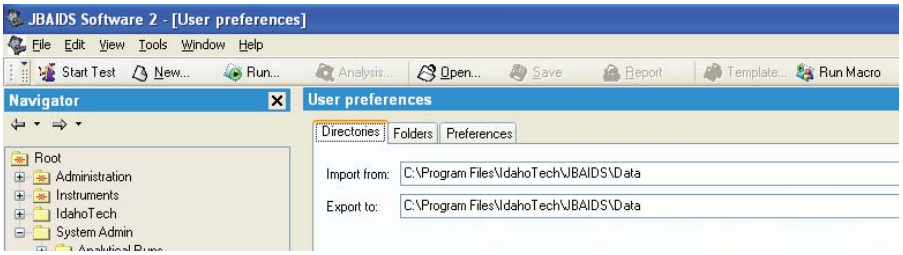
Specifying User Preferences

User preferences specify the following:

- Default directories to import files from and to export JBAIDS software files to
- The default database folders in which to save JBAIDS software items, such as analytical run, macros, and queries
- Which chart and sample preference item to apply as the default, when there are multiple instances of a preferences item.

To specify user preferences

1. Open the **User preferences** item.
2. To specify import/export directories, select the **Directories** tab (if not currently selected).



3. In each box, type a directory path on your local computer or network

   Or

   Click , then navigate to a location on your local computer or the network, then click **OK.**
4. To specify default folders, select the **Folders** tab.
5. In each box, type the path for the folder location in the N**avigator**

   Or

   Click to display a **Navigator.** Select the folder you want, then click **OK.**
6. To specify a preference item as the default, select the **Preferences** tab.
7. In each box, select the preference item you want to specify as the default for the preference type.
8. Click **Save** to save all the user preferences.

JBAIDS SOFTWARE CHARTS

The JBAIDS software allows you to print, export and copy data or images as well as change the display of charts.

Printing, exporting, and copying charts

You can print any chart displayed in JBAIDS software. You can also export the chart image and the chart data separately, or copy and paste the image or the data into other programs.

Print a Chart

1. In the work pane, select the chart you want to print.
2. Right-click within the chart boundaries, then select **Print.**
3. A setup window is displayed. To change the graph margins, and therefore the size of the graph, click and drag the gray margin lines that surround the graph image.

Tip: You can resize the dialog box to make it easier to adjust the graph margins.

5. If necessary, select a printer. (Your Windows printer is selected by default).
6. To change printer configuration options, click **Setup.**
7. A standard Windows printer setup dialog box is displayed. Enter the necessary information, and then click OK.
8. Select **Portrait** or **Landscape.**
9. Click **Print.**

Export a Chart Image

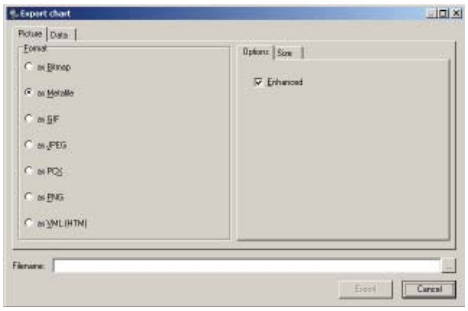
1. Display the chart you want to export.
2. Right-click within the chart boundaries, then select **Export.**
3. On the **Picture** tab, under **Format,** select the graphic format in which you want to export the chart.
4. If an **Options** tab is displayed (on the right), select conversion options as needed. The tab is

not displayed for all graphic formats. If the tab is displayed, the options vary, depending on the format you selected.

5. To change the size of the exported image, select the **Size** tab, then enter the new width and height values. Select **Keep aspect ratio** if you want to maintain the proportions of the chart.
6. Click (to the right of the **Filename** box), to open a **Save As** dialog box.
7. Browse to the location where you want to save the exported chart image, enter a name for the image, then click **Save.**
8. Click **Export** to export the chart image.

Export Chart Data

1. Display the chart containing the data you want to export.
2. Right-click within the chart boundaries, then select **Export.**
3. An **Export Chart** dialog box opens.



4. Select the **Data** tab.
5. In the **Series** box, select the data item you want to export.

   The items vary, depending on the type of chart.
6. In the **Include** box, select the text labels to export with the data.
   - Point Index—Numbers each row
   - Point Labels—Identifies the acquisition points in each sample
   - Header—Provides informational data for each row
7. In the **Format** box, select a format for the exported data.
   - Text—The data is exported as a text (.txt) file
   - XML—The data is exported as an XML (.xml) file
   - HTML Table—The data is exported as an HTML (.html) file
   - Excel—The data is exported as an Microsoft Excel file
8. If you selected **Text** as the format, select a delimiter (data separator) in the **Delimiter** box. (Default is Tab)
9. Click (to the right of the **Filename** box), to open a **Save As** dialog box.
10. Browse to the location where you want to save the exported data, enter a name for the data file, then click **Save.**
11. Click **Export** to export the data.

Copy a Chart Image or Chart Data

1. Display the chart you want to copy.
2. Right-click within the chart boundaries, then select **Copy to clipboard.**
   The chart is saved as a bitmap and the data is saved as text.
3. To paste the chart image, open a graphics application such as Paint, then press Ctrl-V.
4. To paste the chart data, open a text editor such as Notepad, then press Ctrl-V.

Zooming and Panning to View Chart Details

You can enlarge a portion of a chart as many times as necessary to view important details.

To zoom

1. Place the cursor above and to the left of the chart area you want to enlarge.
2. Click and drag the mouse pointer down and to the right. (The pointer changes to a rectangle.) Release the mouse button when the rectangle covers the area you want to enlarge.The area within the rectangle is enlarged to fill the work pane.
3. Repeat **Step 2** as often as necessary until the chart details are as large as you want.
4. To restore the chart to its original size, click and drag the mouse pointer up and to the left. (Do this only once to restore the chart to its original size.)

MAINTENANCE: USING SELF-DIAGNOSTIC TOOLS

JBAIDS software includes the following diagnostic tools used to monitor the JBAIDS instrument's performance:

Note: Close instrument editor before performing a run.

- Instrument self-test
- Instrument logs
- Software messages

Performing an Instrument Self-Test

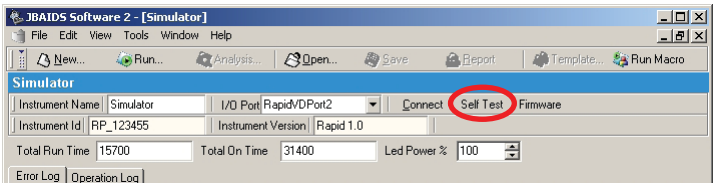
The instrument self-test checks basic instrument functionality, such as heating to the correct temperature and rotating the carousel. To perform a self-test, the instrument needs to have the power turned on, an empty carousel in place and be properly connected to the computer.

Note: Be sure that there are no samples in the carousel when running a self-test.

To perform an instrument self-test

1. In the **Instruments** folder of the **Navigator,** double-click the instrument name to open the **Instrument** window.

2. Click **Self-Test** on the instrument toolbar. The software is locked while the self-test is performed.



If an error occurs, the self-test displays an error message and logs the error to the instrument's error log. See the next section for information about the error log.

If there are no errors, the software displays **Self-test passed** when the self-test is finished.

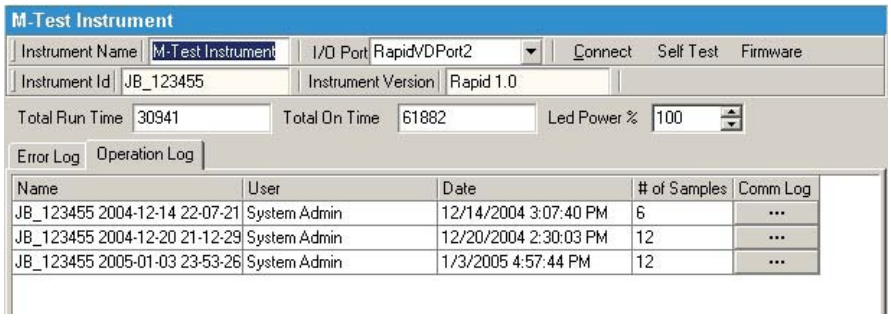
Note: If the LED on the deck of the instrument continues blinking after the self-test is completed, then power off the instrument and let it sit for 5–10 seconds before turning it on again. If light continues to blink, call ITI Technical Support, 1-800-735-6544 or +1 (801) 736-6354.

Viewing the Instrument Logs

JBAIDS software generates an Error Log and an Operation Log, which are both located on the Instrument window. You do not need to use these logs in normal instrument operation. The logs contain information that may be needed by ITI Technical Support representatives if there is an instrument problem.

To view instrument logs

1. In the **Instruments** folder of the **Navigator,** double-click the instrument name to open the **Instrument** window.
   - Total Run Time is the total amount of time the instrument has spent performing cycling.
   - Total On Time is the total amount of time the instrument has been powered up whether running or not.



2. Select the **Operation Log** tab or the **Error Log** tab to view the related log.

The logs contain the following information:

- The **Operation Log** displays a list of the last 10 runs on the instrument. The log includes basic information about each run, such as the run name and date. A Comm Log button is displayed at the end of each row. Click **Comm Log** to display a list of all the commands executed in this run. After opening, the Comm log data can be saved by clicking **Export** in the header.

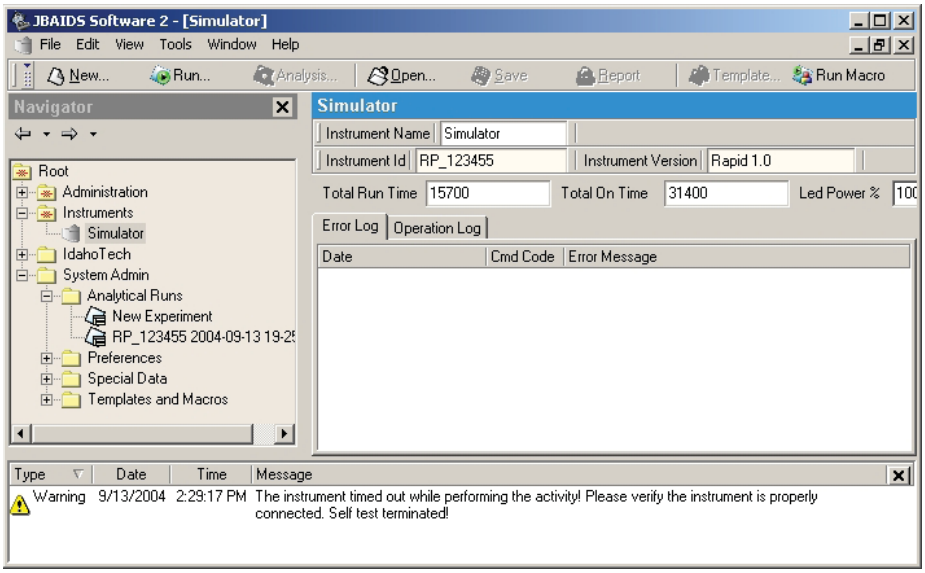
- The **Error Log** lists all errors that have occurred on the instrument. Each error includes an error date, the command code of the error and a remark (the error message). The error log information may be requested by an ITI Technical Support representative if there is an instrument problem. It can be printed by selecting **File** then **Print Window** or saved by pressing **Ctrl+PrtSc** and pasting the print screen into a graphics application.

Viewing Application Error Messages

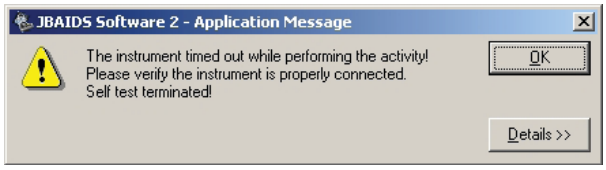
Error messages generated by the software can be displayed in a message pane at the bottom of the JBAIDS software window.

To display or hide the messages pane, follow the steps below

1. Select **View** from the top Menu Bar. This drops down a list of items that can be viewed.
2. Select or deselect **Messages** from the **View** drop-down. The Messages pane displays at the bottom of the software window.



You can double-click on the error message in the Message pane and a window will pop-up containing the message.


JBAIDS Software 2 - Application Message
The instrument timed out while performing the activity!
Please verify the instrument is properly connected.
Self test terminated!
OK
Details >>

Clicking **Details** will give you further information about the error. If contacting ITI Technical Support, it is recommended that you copy and paste this information into any text editor, so that it is available to service personnel.

Error messages are also logged in an application error log file called **JBAIDSError.log** located in the **C:\h\JBAID2\Bin** directory of the JBAIDS software installation path. This log contains a list of application errors generated since the software was installed. Each error entry includes the date and time of the error, the error message, and the exception or call stack. Technical Support will also request this file.

Adding an Instrument Manually

Prerequisites

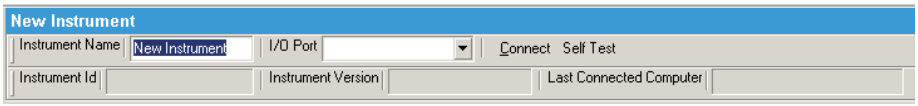
- You must have advanced operator privileges.
- You must know which COM port the instrument is attached to.

To add a new instrument manually

1. Make sure the instrument is physically connected to the computer and is powered on.

Note: Be sure the instrument is powered on before you start the software.

2. Turn on and login to the computer that you want to add the instrument to and then start the **JBAIDS software.**
3. In JBAIDS software, click **New** in the Global Toolbar or select **New** from the **File** menu.
4. Select **JBAIDS instrument**, then click **OK**.



5. The instrument window will open in the work pane.

   In the **Instrument Name** box, type a name for the instrument.
6. In the **I/O Port** box, select the COM port the instrument is attached to.

Note: The default port for the ToughBook is COM 1.

7. Click **Connect.**

   The software finds the instrument connected to the designated COM port and then automatically fills in the remaining boxes.

   The instrument is added to the current JBAIDS software database, and its name appears in the Instruments folder in the **Navigator**. The instrument name will now be included in the list of available instruments in the Run module, so the instrument can be selected for a test.

Adding an Instrument by Searching

Prerequisites

You must have advanced operator privileges.

To allow the software to detect a new instrument

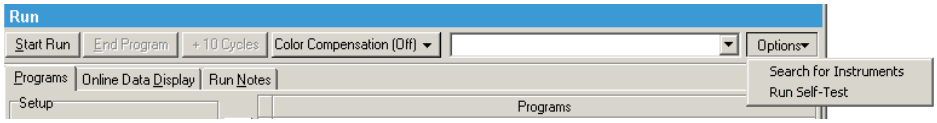
1. Make sure instrument is physically connected to the computer and is powered on.

Note: Be sure the instrument is powered on *before* you start the software.

2. Turn on and login to the computer, then start the **JBAIDS software.**

3. In JBAIDS software click **Run** in the toolbar to open the **Run** module.
4. Click **Options,** then select **Search for instruments.**

   The Options button is located next to the instrument box in the Run window.



   The Discover Instruments dialog box opens.

5. If you know the instrument's COM port, select **Find on selected com port,** then select the port from the pull-down list. If you do not know the port, select **Auto – Detect.**
6. Click **Next.**

   If the software detects a new instrument that has no entry in the current JBAIDS software database, it prompts you to provide a name for the instrument. Enter a name, then click OK.

   Or

   If no instruments are found, the software displays "Unable to find any instruments." Make sure the instrument is connected and powered on, then click **Back** to restart the search. If the instrument is still not detected, then see Chapter 6, *Maintenance and Troubleshooting*.

   After instruments are found, the dialog box displays either the instrument connected to the designated COM port or all the instruments connected to the computer.
8. Select the new instrument you want to add to the database, then click **Finish.**

   Each new instrument is added to the JBAIDS software database, and its name is added to the Instruments folder in the **Navigator** and to the list of available instruments in the Run module.

Adding an Instrument During an Analytical Run

In the following circumstances, a new instrument can be added to the database during a run:

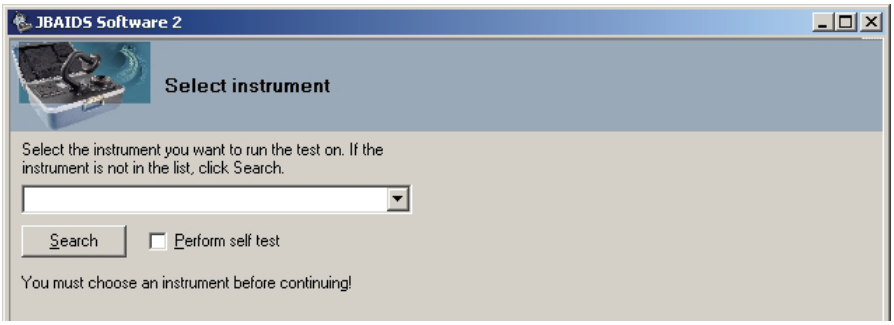
- If the new instrument is the only instrument connected to the computer and there are no instruments currently in the list of available instruments. When the analytical run starts, the software searches the computer's communications ports, finds the connected instrument, and displays a dialog box used to name the instrument. The instrument is then automatically added to the database and to the list of available instruments in the Run module.
- An instrument is connected to the same COM port as a previous instrument, and the previous instrument is selected from the instrument list. When the analysis run starts, the software states that the previous instrument cannot be found, but that a new instrument is connected to the same port. The software may display a dialog box used to name the instrument. The instrument is then automatically added to the database and to the list of available instruments in the Run module.

Connecting to an Instrument

1. If the message appears that an instrument cannot be found, a **Select Instrument** window may appear asking you to manually identify the instrument. Identify the instrument using the drop-down menu. Select the desired instrument, and click **Next**. If you would like to perform a self-test after connecting to the instrument, click the **Perform self-test** box. The instrument self-test checks basic instrument functionality, such as heating to the correct temperature and rotating the carousel.

Note: Samples should not be placed in the carousel prior to a self-test.

2. If there are no instruments listed, be sure that the instrument is turned on and connected with the serial cable to the computer. If an instrument is powered on and connected to the laptop via the serial cable and there is not an instrument listed in the drop-down menu, click the **Search** button.

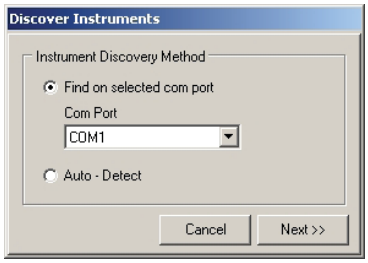

JBAIDS Software 2
Select instrument
Select the instrument you want to run the test on. If the instrument is not in the list, click Search.
Search
Perform self test
You must choose an instrument before continuing!

3. This window allows you to search the computer for connected instruments. This window has two options:
   - Find on selected com port (choose this option if you know the COM port the serial cable is plugged into)

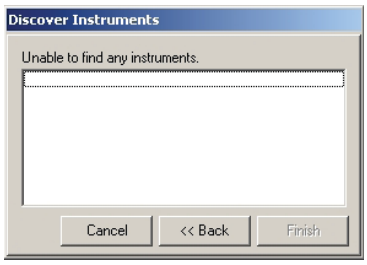
Note: For ToughBook Laptops, the desired COM port is COM1. This option provides a drop-down menu that displays the COM ports that are built into the computer. By selecting this option, it forces the computer to search the selected port. Locate the COM port on the case of the computer to which the instrument serial cable is connected. Match the COM port with the selection in the drop-down menu and select **Next**.

   - Auto-Detect (choose this option if you do not know the COM port)

     This option will search all built-in COM Ports and try to automatically identify an instrument. Select Auto-Detect and select **Next**.



4. After the software searches the COM Ports, a list of connected instruments is displayed. Select the desired instrument and click **Finish.** If this window does not display any instruments, and there is a message, which states that it was **Unable to find any instruments,** confirm that the serial cable is tightly connected to both the instrument and the laptop**.** If this does not resolve the problem then refer to "Troubleshooting," in Chapter 6, *Maintenance and Troubleshooting,* for troubleshooting instructions.



Removing an Instrument

Prerequisites

You must have advanced operator privileges.

If an instrument is no longer available for use, it should be removed from the JBAIDS software database **and** from the list of known instruments.

To remove an instrument from the database

1. To remove the instrument from the current database, open the **Instruments** folder of the **Navigator,** then right-click the instrument name.
2. Click **Delete.**

   You are prompted to confirm the deletion.
3. Click **Yes.**

To remove an instrument from the known instrument list

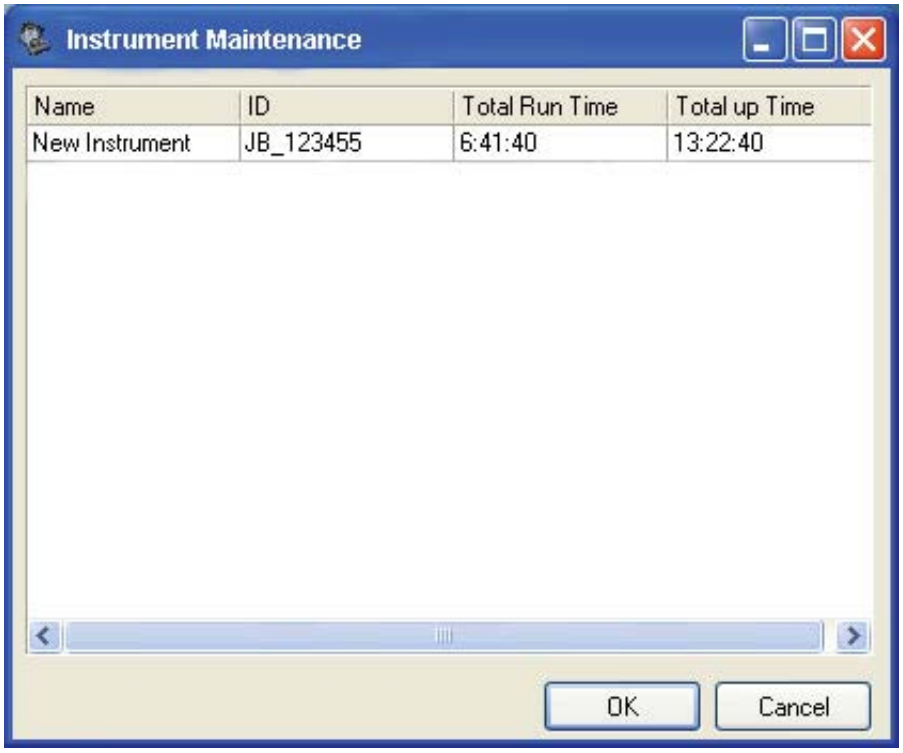
1. To remove the instrument from the list of available instruments in the Run module, from the **Tools** menu, select **Manage Known Instruments.**

   The list of instruments is displayed.
2. Select the instrument you want to delete, then click **Delete.**

Instrument Maintenance

The maintenance module is primarily a usage tracking device. Instrument Name, ID, Total Run Time and Total up Time are displayed. This information is from the internal instrument counters and is instrument specific, not computer specific.

To access the **Instrument Maintenance Log**, go to the Front Screen of the software and click on the **Maintenance** option.



- **Total Run Time** is the total amount of time the instrument has spent performing cycling expressed in hours, minutes, and seconds.
- **Total On Time** is the total amount of time the instrument has been powered up.

CHAPTER 5:

JBAIDS DIAGNOSTIC SOFTWARE

Introduction

The JBAIDS Diagnostic Software performs runs that are intended for use as *in vitro* diagnostic (IVD) products. It includes a step-by-step Wizard that allows operators to: run specific IVD assays; have runs analyzed by the software; and print a specific report. The JBAIDS Software includes two databases: a “Traceable” database and a “Surveillance” database. Chapter 4, *JBAIDS Software*, describes the Surveillance database and software functions in detail. This chapter describes how to use the instrument and software with IVD assays using the Traceable Database.

The features of the Traceable mode are described below:

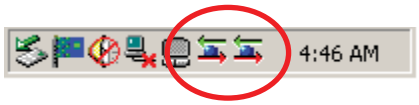
- The user can run only assays that are intended for use as IVD products.
- The user can run tests only by using the JBAIDS Wizard.
- The instrument settings, use of controls, and data analysis procedures are predefined and cannot be changed.
- Test reports generated by the Wizard contain a statement that the test is “**For In Vitro Diagnostic Use**.” Test reports that are not so identified should not be used for diagnostic purposes.
- Test records cannot be deleted or altered. If a change is made to a test record, the user is required to enter change notes, and a new revision of the test record is generated. See “Change History and Audit Trail Information” in this chapter for more details.
- All users have limited rights in the software, no matter what privileges are assigned to their user accounts. Users cannot create new test protocols or run non-IVD assays in the Traceable database.

Starting JBAIDS Diagnostic Software

The JBAIDS instrument features a database (Exor) separate from the program software where all of the analysis information is stored. The information includes run and analysis data, user account information, software preference settings, and instrument information. The Exor database may be installed on the computer connected to the JBAIDS instrument or on another computer on the same network. Exor must be running on the desired laptop computer before the JBAIDS program software can be used.

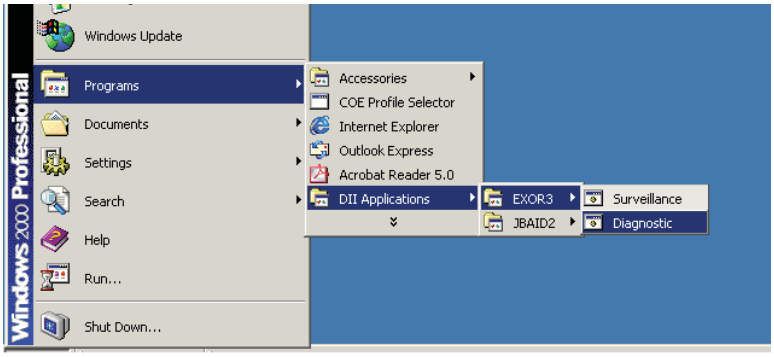
1. Log in to a COE laptop as a designated user as described in Chapter 4, *JBAIDS Software*, “Logging into a COE System.”

2. Exor automatically starts upon login to a JBAIDS laptop. The system tray in the bottom right corner of the screen will contain two sets of paired red and green arrows, one for Surveillance and one for Diagnostic.



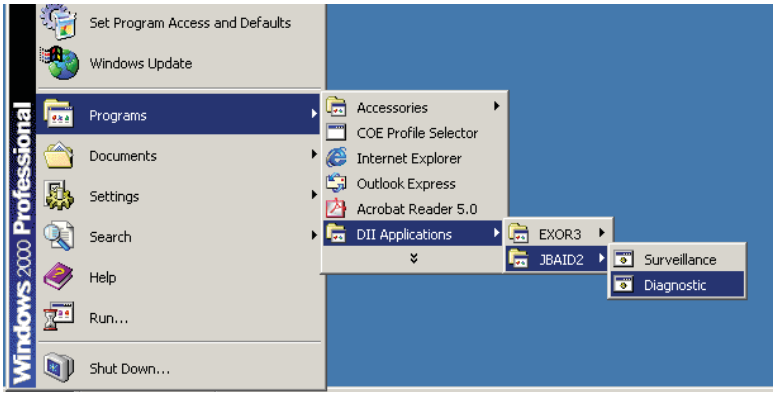
If Exor does not auto-start, use the following steps to start Exor:

1. Locate the JBAIDS Software program under the **Start Menu**, in the **Programs** folder, in the DII Applications/EXOR3 folder. Open the program called **Diagnostic**.
2. Once Exor is opened, the icon will appear in the System Tray.



To start the JBAIDS Software:

Locate the JBAIDS Software program under the **Start Menu**, in the **Programs** folder, in the DII Applications/JBAIDS2 folder. Open the program called "**Diagnostic**."



STARTING THE DIAGNOSTIC WIZARD

Both operators and advanced operators of the JBAIDS instrument must execute a Wizard to run an analysis of diagnostic samples. The Wizard leads the operator step-by-step through the process of selecting one or more tests, entering the kit information, naming the samples, saving the test, loading the carousel, starting the run, viewing results, and printing a report.

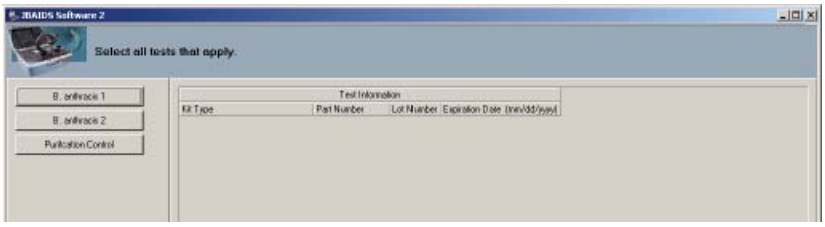
This section describes the Wizard windows and the user's workflow at each step.

1. Log in to the JBAIDS Software. For instructions on starting the software, see the previous section, "Starting JBAIDS Diagnostic Software."

   The front window of the software is displayed.

2. Click **Start Test** to begin the Wizard. If the software cannot find the instrument, see "Connecting to an Instrument" at the end of this chapter. If the software connects to an instrument, continue the steps below.

3. The Diagnostic Wizard displays a list of available *in vitro* diagnostic assays and a purification control button. Refer to the "Purification Control" section for more information concerning use of the Purification Control option.



4. Click a kit type button for each assay to be included in this JBAIDS run. You can select more than one pathogen target to be analyzed during a run. Click the **Purification Control** button only if a purification control will be included.

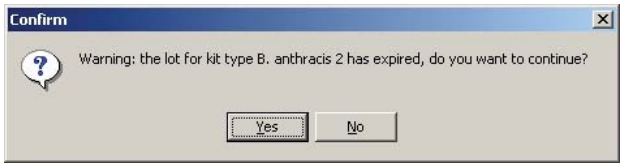
Note: Selecting at least one RNA assay will cause the Wizard to perform a reverse-transcription step and then proceed directly to PCR without user input. DNA and RNA assays can be run at the same time without detrimental effect to either.

5. Enter the **Lot number** and the **Expiration Date** for each selected test. These numbers are printed on the Reagent box or foil pouch label.

   The software will automatically enter the Kit Type and the Part Number for each selected test.

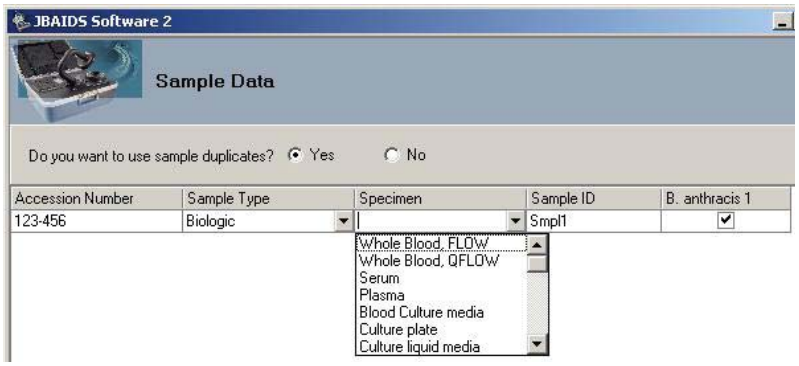
Note: Do not use the lot number printed on the reagent vial.

Note: If you entered an Expiration Date that is in the past, a message box appears that states that the reagents are expired.



Expired reagents should not be used for diagnostic applications. If expired reagents are used, the test report includes the statement "**Expired Kits Used**."

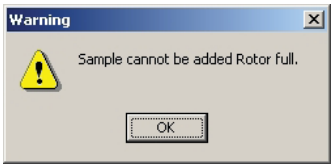
6. Once all of the information is entered for each assay, click **Next**.
7. The Sample Data window will appear. This window lets you add the samples you will be running for each selected assay.



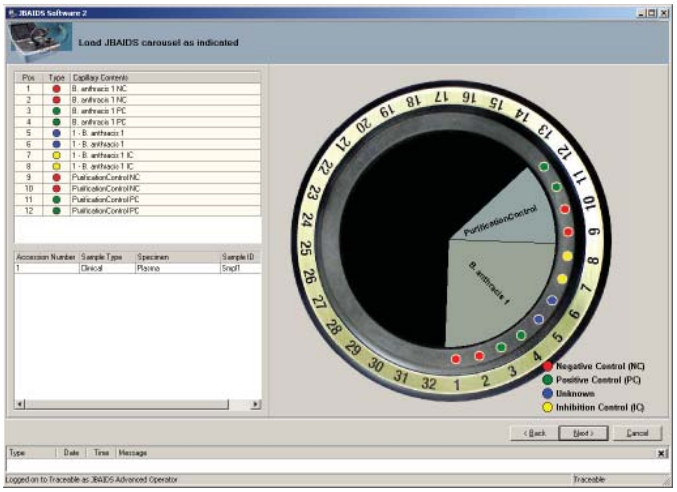
- To add a sample, click the **Add Sample** button located in the bottom right of the window.
- To delete a sample, select the desired sample and then click the **Delete Sample** button in the bottom right of the window.

8. For each sample that is added, you will need to define the following fields:
   - **Accession Number (Accession No.)**—Alpha-numeric entry provided with clinical sample
   - **Sample Type** (pull down menu option)—Clinical
   - **Specimen** (pull down menu options)
   - **Sample ID**—Enter information to identify the specific sample. Sample ID is often provided with the sample for analysis. If the user does not enter a sample ID, a default value of Smpl*n* (where *n* = number of the sample) will be provided by the software.
   - **Target check box**—There will be a check box for each pathogen target that was selected in the first window.

The software automatically calculates how many samples you will be running based upon the options you have selected. If your selections require more than 32 capillaries to complete the testing, you will be warned with the following message.



9. After you click on **OK**, you can make changes to your test and delete tests. To add a test, use the **Back** button to go back to the previous screen. When your test is set up, click **Next** to view the Load window.
10. After all of the samples and their characteristics have been entered, click **Next** to display a Loading window that illustrates how the sample carousel should be loaded.



The Loading window illustrates the correct placement of capillaries in the carousel.

The Wizard displays a sample list that includes the carousel position and the contents of each capillary.

- Negative Controls are designated NC
- Positive Controls are designated PC
- Unknown Samples
- Inhibition Controls are designated IC

The Wizard automatically enters two positive control capillaries (PC) and two negative control capillaries (NC) per selected assay. The Wizard also adds two unknown and two inhibition control capillaries (IC) per **sample**. If the Purification Control was selected, the Wizard automatically enters two PC and two NC capillaries for the Purification Control assay to the end of the run.

11. Loading the Carousel
    a. Remove the carousel by giving it a quarter turn counter-clockwise to unlock it from the instrument. Lift the carousel straight up and out of the machine to avoid breaking capillaries on the chamber fan. Appropriately discard capillaries from previous test.

WARNING: Capillary breakage is a significant source of amplicon contamination. If a capillary breaks, immediately execute decontamination procedures after any capillary breakage or sample spill occurs, taking care to follow recommended procedures as written. See Chapter 2, "Safety Assessment of Risk Related to Capillary Breakage."

b. Load the prepared samples into the sample carousel using the Loading Window information as a guide. After the samples are carefully placed into the carousel make sure that all capillaries are seated correctly; they should be pushed down gently to seat them in the proper locations.

Note: ALL POSITIONS INDICATED BY THE SOFTWARE WIZARD MUST CONTAIN A FILLED CAPILLARY. If the instrument does not detect a capillary in a position designated to have a capillary, the run will abort. An empty capillary will also cause the run to abort; ensure that reaction mixture has been forced into the bottom of each capillary after centrifugation.

c. Replace the loaded carousel into the instrument by aligning the gold arrows on the outside of the carousel and the deck plate.

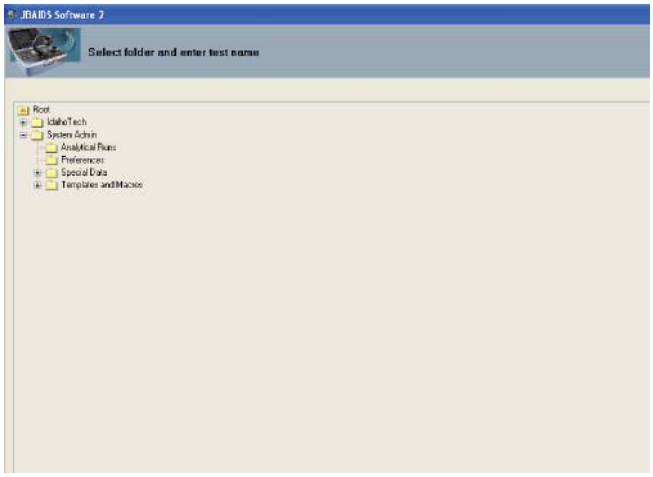
d. Lock the carousel into place by giving it a quarter turn clockwise.

e. Rotate the heating duct assembly over the samples to perform a test.

WARNING: If capillaries are not properly seated, the fluorimeter readings may be excessively noisy, causing uncertain, invalid, or erroneous readings. Do not force the capillaries into the carousel, or they will break. Lock the carousel into the instrument by aligning the gold arrows and rotating it clockwise to its locked position.

12. With the carousel locked into place and the heating duct (snorkel) assembly in its closed position, click **Next**.

    The next screen prompts you to save the test.



13. Save the test in the Analytical Runs folder under your user folder, or another designated folder, in the Navigator. The default name for the test is the Instrument ID, plus the current date and time in Universal Time (Greenwich Mean Time). It is suggested that users add additional information to the default name rather than replacing the text. This allows users to quickly determine the date of the run and the serial number of the instrument used.

14. Keep the default file location and name, or select a new location, and/or enter a new name for the JBAIDS run file.
15. Click **Next** to save the test. Make sure the carousel is in its locked position and the heating duct (snorkel) assembly is in its closed position, rotated over the carousel. A message box prompts you to start the test. Click **Start Test** to begin the run.

JBAIDS Run Wizard
Your test is now ready.
Close the JBAIDS snorkel, then click Start Test to begin the run.
Start Test
Cancel

Note: If a sample is not found during the run, then the run will abort. Use the following steps to troubleshoot**:**

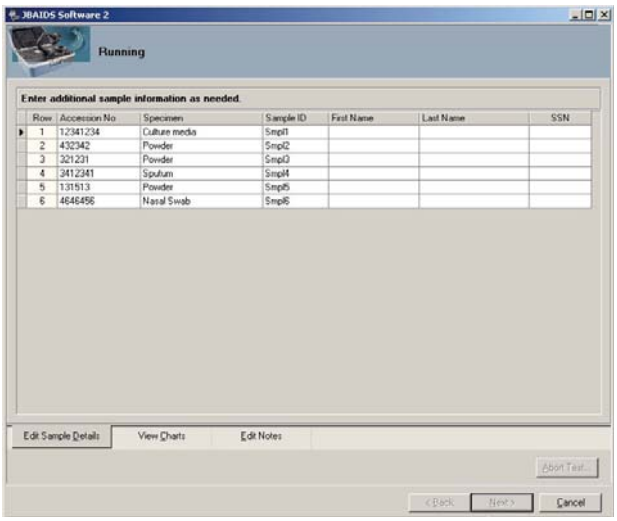
- Replace any missing capillaries with appropriate samples.
- Check that your samples have been centrifuged down to the bottom of the capillary and volumes are roughly equivalent between all capillaries.
- Ensure that all capillaries are firmly seated.
- If none of these apply: Then replace any capillaries that failed with newly prepared freeze-dried reagents (the same sample extraction can be used).
- Repeat **Start Test**.
- For further troubleshooting see *Chapter 6, Maintenance and Troubleshooting.*

16. The instrument will begin cycling.

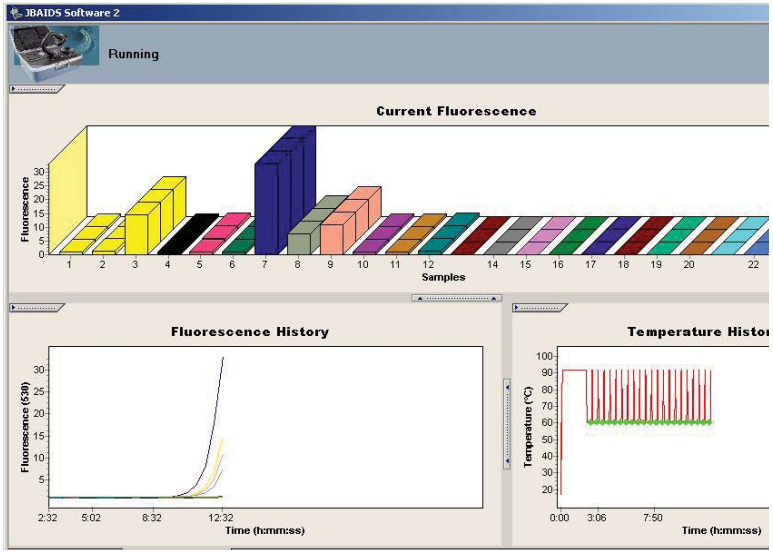
    If you need to stop the analytical run before it is finished, click **Abort Test**. When you abort a test, the data that has been generated for that test will not be available for analysis, but can be viewed in the Raw Data tab.

    While the test is running, some sample data can be modified. After the run in the Diagnostic option database is finished, a Change Log must be completed prior to saving the modification.

    The default screen is the Edit Sample Details as shown below. This window allows you to enter additional information about each sample including first and last name and social security number.



17. The **View Charts** tab displays charts of real-time data as the instrument runs.

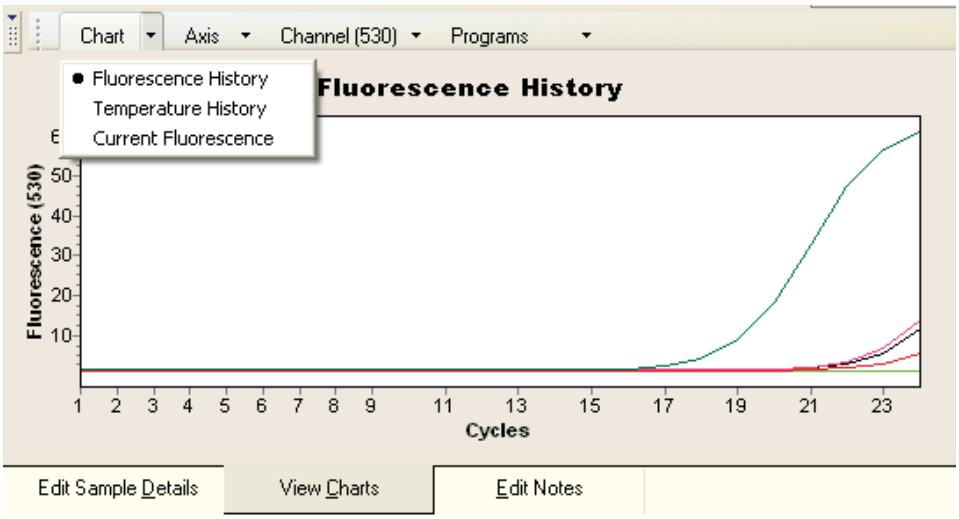


18. You can select which charts you want to see.

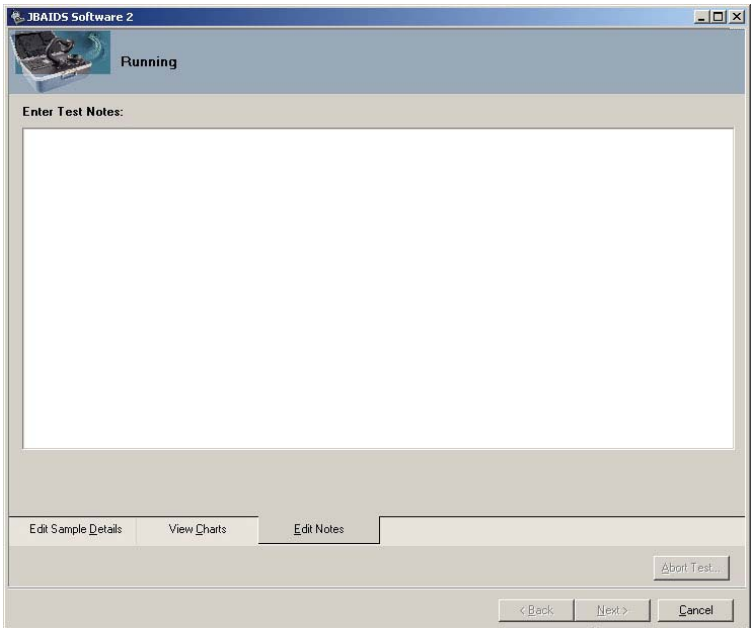
    To select a chart, click the handle in the left corner of the desired chart, then from the Chart menu, select the chart type.

    Three charts are available:

    - Fluorescence History
    - Temperature History
    - Current Fluorescence

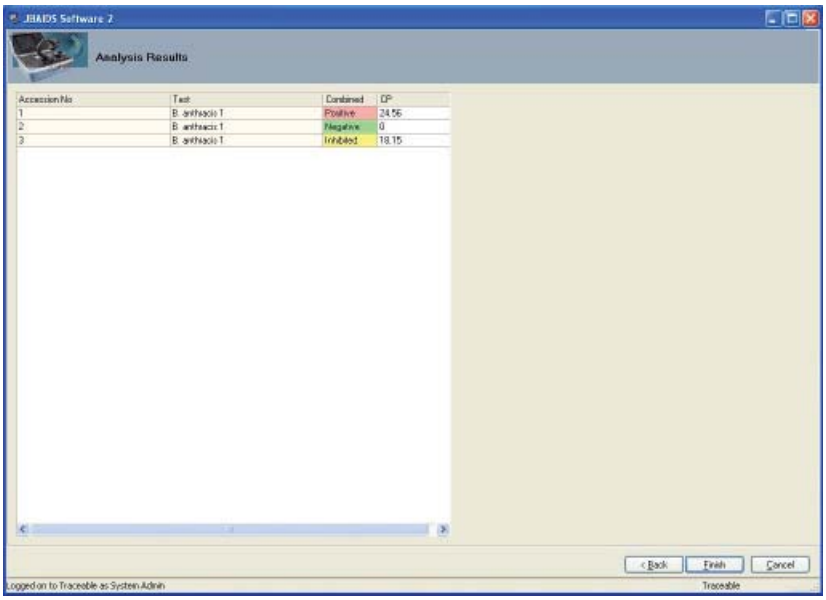


19. To enter additional information about the analytical run, click the **Edit Notes** tab. The Edit Notes tab is shown below.



20. When the test is finished, the message **Run Complete** will appear in the bottom of the window. Click **Next** to view the results.

    The Analysis Results window is shown below.



21. For each sample, the results include the following:
    - **Accession No.**
    - **Test**
    - **Combined Result**— a combination of the control results and the unknown results.
    - **Cp value for each sample**—see Appendix A for information about Cp values.

    The Results window displays results only for the capillaries that contain unknown samples.

The Possible Results are:

Positive	A red positive call indicates that the target was identified in that sample and the run controls were successful. A sample that is detected as positive will generate an audible signal in the software.
Negative	A green negative call indicates that the target was not identified in that sample and all the run controls (NC, PC, and IC) were successful.
Uncertain	A yellow uncertain call indicates that the instrument was unable to interpret the data and the run controls were successful.
Invalid	A yellow invalid call indicates that a PC or NC failed. All samples connected to that control would be invalid.
Inhibited	A yellow inhibited call indicates that PC and NC were successful and one or more inhibition capillaries associated with that sample failed.

Positive, Invalid, Inhibited and Uncertain results should be referred to a supervisor or followed up per the laboratory's procedures. Additional information regarding follow-up actions may be included in freeze-dried reagent product inserts. When there is a positive call, an audible tone

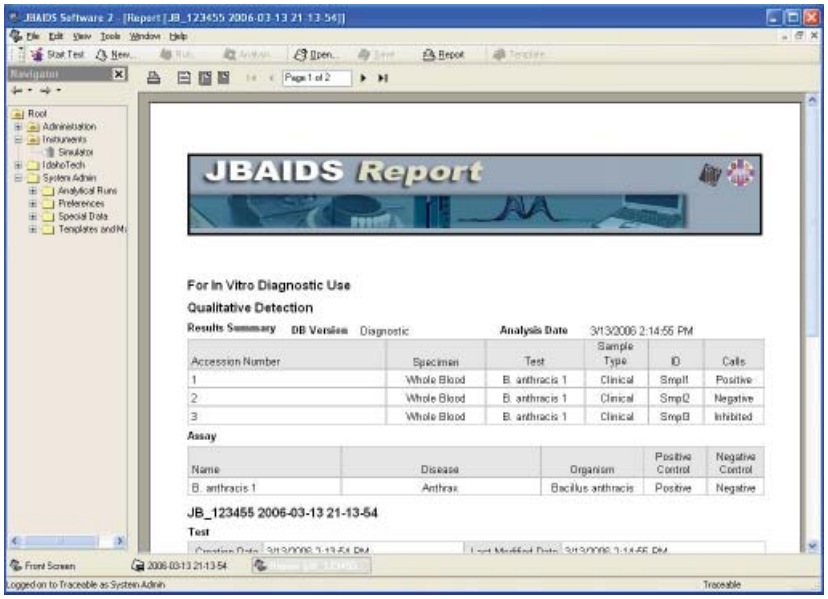
is sounded and a message is displayed that instructs the user to read the package insert or to refer to their clinical laboratory procedures for information about how to interpret the positive call.

22. Click **Finish** to view a report of the test results. The report contains the following information:
    - Diagnostic run summary information (such as name and date)
    - Diagnostic run protocol
    - Sample information
    - Instrument information
    - Diagnostic results and charts
    - Kit name, part number, lot number, and expiration date
    - Change History—note that Revision 1 is the initiation of the Wizard, Revision 2 is the completed run before analysis, and Revision 3 is after the Wizard adds an analysis. Revision 3 is the first version seen by users.
23. Click **Print** to print the report.

    You cannot modify the report content or display. You cannot save the report separately, but the report can be regenerated and opened whenever desired.

In Vitro Diagnostic Statement

Runs performed using the Diagnostic Wizard will contain the statement “For In Vitro Diagnostic Use.” When the IVD statement is printed on the report, it indicates that the test was performed according to product specifications (e.g., appropriate use and interpretation of controls, application of correct cycling and analysis settings) and that the results can be used for human diagnostic applications. The statement will only print on a report that has been performed using the Diagnostic Wizard and for which the audit trail (see “Change History and Audit Trail” later in this chapter) is intact. Test results that are imported, exported, or not run using the Diagnostic Wizard will not contain this statement and should not be used for human diagnostics. The test results that are imported or exported will contain the statement “For Investigational Uses Only. The performance characteristics of this product has not been established.”



Purification Control

Purification controls are used to monitor the sample extraction/purification component of the test system. Sample purification is a critical step in the testing process. Ineffective sample purification can lead to false negative test results either by failure to extract the nucleic acid from the target and/or by failure to remove PCR inhibitors from the samples.

Purification controls typically involve processing and testing a known positive and known negative sample in parallel with the unknown sample(s). It is expected that the known positive sample will test positive, indicating that the sample purification was performed correctly, and that the known negative sample will be negative, indicating no cross contamination during processing. Please consult the package insert for the specific freeze-dried reagent you are using for a detailed description of setting up and testing purification controls.

To include a purification control in a JBAIDS run, select the **Purification Control** button on the assay selection screen of the Diagnostic Wizard. Selecting this option will result in the addition of two positive purification control capillaries and two negative purification control capillaries to the end of the test run.

Note: Each run can only include one set of purification control capillaries. Any additional purification controls must be tested in a separate run.

Place the capillaries derived from the positive and negative purification control in the appropriate locations in the carousel. At the conclusion of the run, the purification control will be considered a ‘Success’ if both of the positive purification controls amplified AND if neither of the negative purification controls amplified. The result for the control will be ‘Invalid’ if either of the positive control capillaries fails to amplify OR if either of the negative control capillaries demonstrates amplification. As opposed to the other controls (PC, NC and IC), the result of the purification control will not affect the results of the Unknown samples included in the run. This is because a single purification control may be associated with one sample or with many samples. If the purification control is Invalid, it is possible that sample purification was not successful and that the results of unknown samples that were processed alongside the controls may not be valid. These cases should be handled in accordance with your laboratory’s procedures for responding to a failed purification control or referred to a supervisor.

QUALITATIVE DETECTION ANALYSIS

The Qualitative Detection module analyzes unknown samples for the presence of a particular target based on whether the data shows target amplification. The analysis does not quantify the amount of target DNA. A Qualitative Detection analysis is automatically performed on any Diagnostic Run performed using the Wizard.

Controls

Controls are expected to behave in a certain way, depending on the purpose of the control. If they fail to behave as expected, the unknown sample reactions associated with the controls are considered failures.

The following types of controls are used in a Diagnostic analysis:

Positive control (PC): Once reconstituted, the positive control contains all components needed for performing PCR, including the nucleic acid target for which the unknown samples are being analyzed. A positive control is located in a separate tube from the unknown samples, and its results apply to all the unknowns for the specific assay in the run. If amplification does not occur in both of the PC capillaries, then the control fails and all associated samples are called 'Invalid'.

Negative control (NC): Contains all components needed for performing PCR, but does not contain the nucleic acid target for which the unknown samples are being analyzed. A negative control is located in a separate tube from the unknown samples. A negative control applies to all the unknowns for the specified assay in the run. If amplification occurs in either of the NC capillaries, then the control fails and all associated samples are called 'Invalid'. In this case, the NC is contaminated, and unknown samples may also be contaminated.

Inhibition Control (IC): An inhibition control is a positive control to which unknown sample is added. They are always paired with their unknown samples. Inhibition controls are considered a success if they amplify within a designated number of cycles of the Positive Control for the same assay and have signal increase greater than the designated range. The inhibition control is used to determine the presence of inhibitors, which might affect detection of target sequences. If either of the inhibition control capillaries fail to demonstrate the expected level of amplification, the unknown sample associated with the inhibition control will be called 'Inhibited". The freeze-dried reagent product insert provides instructions for follow-up testing.

Purification Control: See "Purification Control" section.

Type of Sample	Positive Control	Negative Control	Inhibition Control	Unknown Sample
Type of Tube used	Positive Control	Negative Control	Inhibition Control	Unknown
Template already added to tube?	Yes	No	Yes	No
What is added	Water and Reconstitution Buffer	Water and Reconstitution Buffer	Sample and Reconstitution Buffer	Sample and Reconstitution Buffer

How Results are Displayed

The Qualitative Detection module displays three results for each sample: Control, Target, and Combined as shown below:

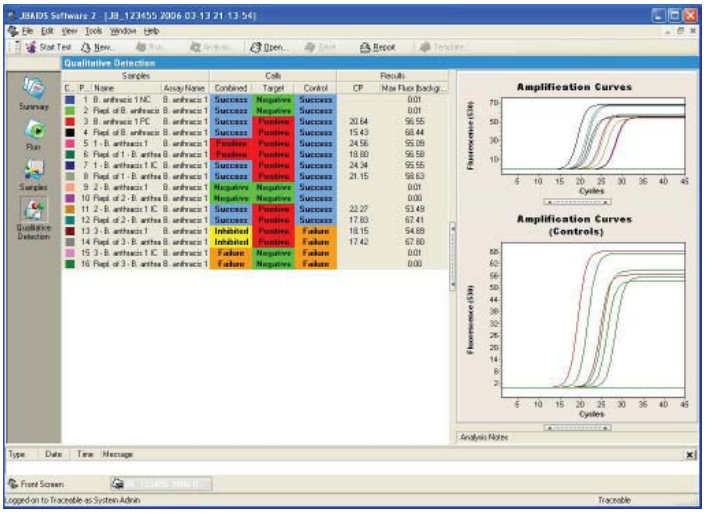
Control result: The Control result displays the Success or Failure for the *combination* of all control replicates that apply to this sample. All the controls that apply to a particular example are treated together. If *any* of the control replicates fail, the Control column displays "Failure." Controls

apply not just to Unknown samples, but also to other controls. For example the failure of a Positive Control will result in control result of 'Failure' for both of the positive control capillaries and all of the related negative controls.

Combined result: The Combined result is based on the Target result and the Control result for all replicates. The possible Combined Calls include Positive, Negative, Invalid, Uncertain, or Inhibited.

Target result: The Target result is the call for the individual capillary based on the amplification profile.

In addition, the Cp value and background subtracted maximum fluorescence are displaced for each capillary.



Possible Results for Control

The success or failure of a control affects whether a sample result is valid.

Success	PC's and NC's	All Negative Control replicates for assay do not amplify. And All Positive controls for the assay do amplify.
	ICs and Samples	All Negative Control replicates for assay do not amplify. And All Positive Control replicates for assay do amplify. And All Inhibition Controls demonstrate expected amplification curves.

Failure	PC's and NC's	Either of the Negative Control replicates does amplify (In this case, samples may be contaminated or incorrectly ordered) **Or** Either of the Positive Control replicates for assay does not amplify (this may be due to presence of inhibitory substance such as bleach)
	ICs and Samples	Any Negative Control replicate for assay does amplify. **Or** Any Positive Control replicate for assay does not amplify. Or Either of the Inhibition Control replicates does not demonstrate expected amplification curves. A failed inhibition control means that the inhibition control and the unknown contain a substance that inhibits PCR reactions. Even if the Unknown sample is Positive, the control is considered failed.

Possible Results for Target

Target result: The Target result is the call for the individual capillary based on the specific capillary's amplification profile.

Positive	PC's and NC's	Individual capillary amplifies.
	ICs	Individual capillary for Inhibition Control amplifies and is above designated fluorescence level and crossing point is within range of positive control.

Negative	PC's, NC's, and Samples	Individual capillary fails to amplify.
	ICs	Individual capillary for Inhibition Control does not amplify or is below designated fluorescence level or crossing point is outside range of positive control.

Uncertain	PC's, NC's, and Samples	Amplification of individual capillary cannot be determined.

Possible Results for Combined

Combined result: The combined call for a sample is determined from the sample's target call (whether the sample shows amplification or not) and from the success or failure of controls that apply to the sample.

Success	PC's and NC's	All Negative Control replicates for assay do not amplify. And All Positive controls for the assay do amplify.
Failure	PC's and NC's	Any Negative Control replicate for the assay does amplify Or Any Positive Control replicate for the assay does not amplify
Positive	For samples	If all controls succeed and if both unknown capillaries are Positive
Negative	For samples	If all controls succeed and if both unknown capillaries are Negative
Uncertain	For samples	If all controls succeed and the unknown capillaries have different calls, or if they are both uncertain
Invalid	For samples	If either a Positive Control or a Negative Control fails, then the combined call for all samples in the test is invalid
Inhibited	For samples	If the Positive Controls and the Negative Controls succeed, but an inhibition control for a sample fails, then the combined call for the associated sample(s) is inhibited

Examples of Results

Example I: Analysis Window

Accession No	Test	Combined
123	B. anthracis 1	Positive
456	B. anthracis 1	Negative
789	B. anthracis 1	Uncertain
ABC	B. anthracis 1	Uncertain
DEF	B. anthracis 1	Uncertain
GHI	B. anthracis 1	Uncertain

Report Results

Qualitative Detection

Results Summary **Analysis Date** 5/13/2005 12:15:19 PM

Accession Number	Specimen	Test	Sample Type	ID	Calls
123	Whole Blood	B. anthracis 1	Clinical	Smpl1	Positive
456	Whole Blood	B. anthracis 1	Clinical	Smpl2	Negative
789	Whole Blood	B. anthracis 1	Clinical	Smpl3	Uncertain
ABC	Blood Culture media	B. anthracis 1	Clinical	Smpl4	Uncertain
DEF	Blood Culture media	B. anthracis 1	Clinical	Smpl5	Uncertain
GHI	Blood Culture media	B. anthracis 1	Clinical	Smpl6	Uncertain

Assay

Name	Disease	Organism	Positive Control	Negative Control
B. anthracis 1	Anthrax	Bacillus anthracis	Positive	Negative

Qualitative Detection Module

Qualitative Detection

Samples				Calls		
Color	Pos	Name	Assay Name	Combined	Target	Control
	1	B. anthracis 1 NC	B. anthracis 1	Success	Negative	Success
	2	Repl. of B. anthracis 1 NC	B. anthracis 1	Success	Negative	Success
	3	B. anthracis 1 PC	B. anthracis 1	Success	Positive	Success
	4	Repl. of B. anthracis 1 PC	B. anthracis 1	Success	Positive	Success
	5	123 - B. anthracis 1	B. anthracis 1	Positive	Positive	Success
	6	Repl. of 123 - B. anthracis 1	B. anthracis 1	Positive	Positive	Success
	7	123 - B. anthracis 1 IC	B. anthracis 1	Success	Positive	Success
	8	Repl. of 123 - B. anthracis 1 IC	B. anthracis 1	Success	Positive	Success
	9	456 - B. anthracis 1	B. anthracis 1	Negative	Negative	Success
	10	Repl. of 456 - B. anthracis 1	B. anthracis 1	Negative	Negative	Success
	11	456 - B. anthracis 1 IC	B. anthracis 1	Success	Positive	Success
	12	Repl. of 456 - B. anthracis 1 IC	B. anthracis 1	Success	Positive	Success
	13	789 - B. anthracis 1	B. anthracis 1	Uncertain	Negative	Success
	14	Repl. of 789 - B. anthracis 1	B. anthracis 1	Uncertain	Positive	Success
	15	789 - B. anthracis 1 IC	B. anthracis 1	Success	Positive	Success
	16	Repl. of 789 - B. anthracis 1 IC	B. anthracis 1	Success	Positive	Success
	17	ABC - B. anthracis 1	B. anthracis 1	Uncertain	Positive	Success
	18	Repl. of ABC - B. anthracis 1	B. anthracis 1	Uncertain	Uncertain	Success
	19	ABC - B. anthracis 1 IC	B. anthracis 1	Success	Positive	Success
	20	Repl. of ABC - B. anthracis 1 IC	B. anthracis 1	Success	Positive	Success
	21	DEF - B. anthracis 1	B. anthracis 1	Uncertain	Negative	Success
	22	Repl. of DEF - B. anthracis 1	B. anthracis 1	Uncertain	Uncertain	Success
	23	DEF - B. anthracis 1 IC	B. anthracis 1	Success	Positive	Success
	24	Repl. of DEF - B. anthracis 1 IC	B. anthracis 1	Success	Positive	Success
	25	GHI - B. anthracis 1	B. anthracis 1	Uncertain	Uncertain	Success
	26	Repl. of GHI - B. anthracis 1	B. anthracis 1	Uncertain	Uncertain	Success
	27	GHI - B. anthracis 1 IC	B. anthracis 1	Success	Positive	Success
	28	Repl. of GHI - B. anthracis 1 IC	B. anthracis 1	Success	Positive	Success

Results

Control Results: Success for all capillaries.

No Negative Control Replicates amplify **and**
All Positive Control Replicates amplify **and**
All Inhibition controls amplify and are above designated fluorescence level and crossing point is within range of average Positive Control crossing point

Combined Results:

123 called positive because both replicates amplified
456 called negative because both replicates failed to amplify
789, ABC, DEF called uncertain because replicates did not agree
GHI called uncertain because both replicates were called uncertain

Example II

Analysis Window

Accession No	Test	Combined
JKL	B. anthracis 1	Invalid
MNO	B. anthracis 1	Invalid
PQR	B. anthracis 1	Invalid
JKL	B. anthracis 2	Inhibited
MNO	B. anthracis 2	Inhibited
PQR	B. anthracis 2	Inhibited

Report Results

Qualitative Detection

Results Summary **Analysis Date** 6/7/2005 3:20:36 PM

Accession Number	Specimen	Test	Sample Type	ID	Calls
JKL	Whole Blood	B. anthracis 1	Clinical	Smpl1	Invalid
MNO	Blood Culture media	B. anthracis 1	Clinical	Smpl2	Invalid
PQR	Whole Blood	B. anthracis 1	Clinical	Smpl3	Invalid
JKL	Whole Blood	B. anthracis 2	Clinical	Smpl1	Inhibited
MNO	Blood Culture media	B. anthracis 2	Clinical	Smpl2	Inhibited
PQR	Whole Blood	B. anthracis 2	Clinical	Smpl3	Inhibited

Assay

Name	Disease	Organism	Positive Control	Negative Control
B. anthracis 1	Anthrax	Bacillus anthracis	Positive	Failure
B. anthracis 2	Anthrax	Bacillus anthracis	Positive	Negative

Qualitative Detection Module

Qualitative Detection

Samples				Calls		
Color	Pos	Name	Assay Name	Combined	Target	Control
	1	B. anthracis 1 NC	B. anthracis 1	Failure	Negative	Failure
	2	Repl. of B. anthracis 1 NC	B. anthracis 1	Failure	Positive	Failure
	3	B. anthracis 1 PC	B. anthracis 1	Failure	Positive	Failure
	4	Repl. of B. anthracis 1 PC	B. anthracis 1	Failure	Positive	Failure
	5	JKL - B. anthracis 1	B. anthracis 1	Invalid	Positive	Failure
	6	Repl. of JKL - B. anthracis 1	B. anthracis 1	Invalid	Positive	Failure
	7	JKL - B. anthracis 1 IC	B. anthracis 1	Failure	Positive	Failure
	8	Repl. of JKL - B. anthracis 1 IC	B. anthracis 1	Failure	Positive	Failure
	9	MNO - B. anthracis 1	B. anthracis 1	Invalid	Negative	Failure
	10	Repl. of MNO - B. anthracis 1	B. anthracis 1	Invalid	Negative	Failure
	11	MNO - B. anthracis 1 IC	B. anthracis 1	Failure	Negative	Failure
	12	Repl. of MNO - B. anthracis 1	B. anthracis 1	Failure	Negative	Failure
	13	PQR - B. anthracis 1	B. anthracis 1	Invalid	Positive	Failure
	14	Repl. of PQR - B. anthracis 1	B. anthracis 1	Invalid	Negative	Failure
	15	PQR - B. anthracis 1 IC	B. anthracis 1	Failure	Positive	Failure
	16	Repl. of PQR - B. anthracis 1 I	B. anthracis 1	Failure	Positive	Failure
	17	B. anthracis 2 NC	B. anthracis 2	Success	Negative	Success
	18	Repl. of B. anthracis 2 NC	B. anthracis 2	Success	Negative	Success
	19	B. anthracis 2 PC	B. anthracis 2	Success	Positive	Success
	20	Repl. of B. anthracis 2 PC	B. anthracis 2	Success	Positive	Success
	21	JKL - B. anthracis 2	B. anthracis 2	Inhibited	Positive	Failure
	22	Repl. of JKL - B. anthracis 2	B. anthracis 2	Inhibited	Positive	Failure
	23	JKL - B. anthracis 2 IC	B. anthracis 2	Failure	Negative	Failure
	24	Repl. of JKL - B. anthracis 2 IC	B. anthracis 2	Failure	Negative	Failure
	25	MNO - B. anthracis 2	B. anthracis 2	Inhibited	Positive	Failure
	26	Repl. of MNO - B. anthracis 2	B. anthracis 2	Inhibited	Positive	Failure
	27	MNO - B. anthracis 2 IC	B. anthracis 2	Failure	Negative	Failure
	28	Repl. of MNO - B. anthracis 2	B. anthracis 2	Failure	Positive	Failure
	29	PQR - B. anthracis 2	B. anthracis 2	Inhibited	Positive	Failure
	30	Repl. of PQR - B. anthracis 2	B. anthracis 2	Inhibited	Positive	Failure
	31	PQR - B. anthracis 2 IC	B. anthracis 2	Failure	Negative	Failure
	32	Repl. of PQR - B. anthracis 2 I	B. anthracis 2	Failure	Negative	Failure

Results

B. anthracis **1**	*B. anthracis* **2**
Control Results Failure for all capillaries for *B. anthracis* 1 assay because capillary 2, a NC replicate, amplifies (is called positive)	**Control Results** Success for PC and NC capillaries, since no NC replicates amplify **and** all PC replicates amplify Failure for IC and sample capillaries because at least one IC for each sample fails to amplify.
Combined Results All samples (JKL, MNO, and PQR) are invalid, independent of target call, due to failure of NC capillary 2.	**Combined Results** All samples (JKL, MNO, and PQR) are inhibited, independent of target call, due to failure of IC capillaries

CHANGE HISTORY AND AUDIT TRAIL INFORMATION

An audit trail allows revisions and changes to each test to be stored and accessed. The audit trail is activated whenever you are logged into a traceable database.

Audit Trail mode affects the following:

- In audit trail mode, it is impossible to overwrite or delete tests or analyses.
- A user is unable to copy a test or save a test with a new name. Names for test records, color-compensation data records, standard curve records and standard melting curve set records must be unique within the database.
- The test is automatically stored when the Wizard is initiated.
- The audit trail stores the following information about each saved version of a test: Date, Operator, Change Notes, and Revision number.
- If a test with an IVD statement is exported and then imported, the imported file does *not* maintain the IVD statement (i.e., the report cannot be used for human diagnostic purposes).

Revisions

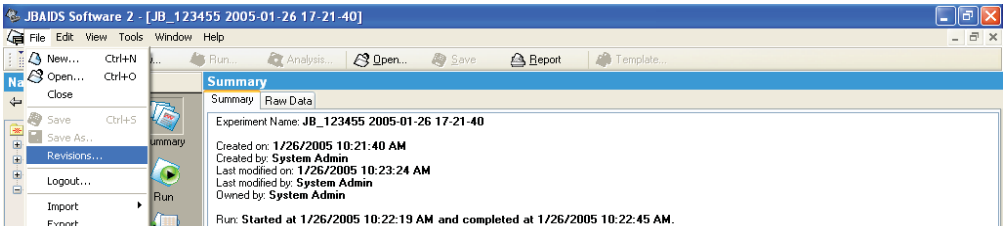
Change notes are required for every change after the completion of the test and analysis.

- Versions 1–3 do not require change notes
- Version 1 is the creation of the run with the Wizard
- Version 2 is created when the run is finished
- Version 3 is saved when the Wizard automatically adds an analysis to a finished run

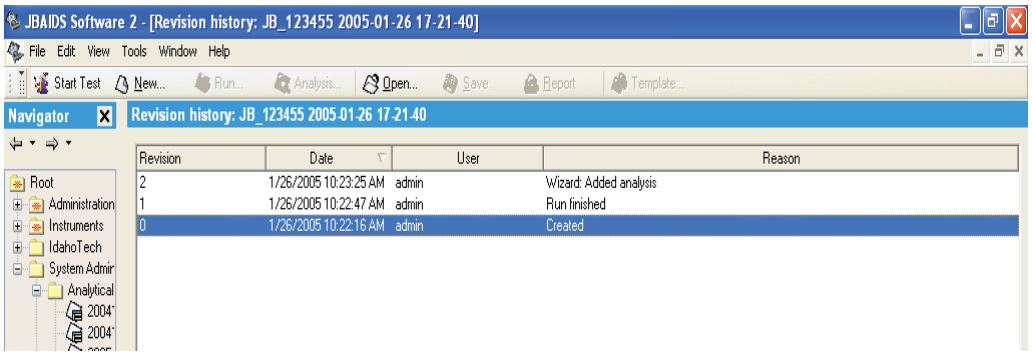
Previous revisions of the test shall be saved in the database as read-only information. The user is able to change only the latest revision of a test. In the Traceable Database, only limited data fields can be changed. These include the run notes, the sample notes, and the patient's name or social security number.

To view revisions:

1. Open the test and go to **File->Revisions**



A Revision menu will appear listing revision numbers, dates, user and reason for change.


JBAIDS Software 2 - [Revision history: JB_123455 2005-01-26 17-21-40]
File Edit View Tools Window Help
Start Test New... Run... Analysis... Open... Save Report Template...
Navigator
Revision history: JB_123455 2005-01-26 17-21-40
Root
Administration
Instruments
IdahoTech
System Admin
Analytical
Revision Date User Reason
2 1/26/2005 10:23:25 AM admin Wizard: Added analysis
1 1/26/2005 10:22:47 AM admin Run finished
0 1/26/2005 10:22:16 AM admin Created

2. A previous revision can be opened by double-clicking on the desired selection. Previous revisions of a test are not visible in the Navigator. The previous revision of the test will open in the work pane with the number of the revision appended to the front of the run name.

   Users can generate a report for previous versions of the test. All reports shall state the version of the test used for the report using the following format: version x of y, where x = the current test version and y = the total number of versions of this test .

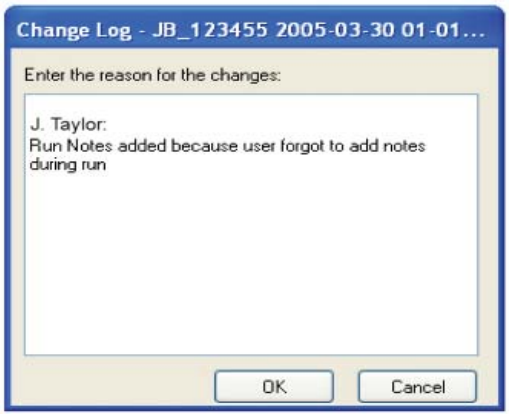
Change Notes

Change notes are added to the audit trail to describe new revisions whenever an experiment is edited, sample information added, or run notes edited. In the example below, run notes were added to an experiment. When the modified run is saved, the user is prompted to enter change notes describing the nature of the changes.

Note: Informative and detailed change notes are *essential* to the audit trail process, so users must enter the following information:

1. Name of user making changes
2. Specific changes made
3. Reasons for making changes

   These change notes are the only specific record of what was changed.


Change Log - JB_123455 2005-03-30 01-01...
Enter the reason for the changes:
J. Taylor:
Run Notes added because user forgot to add notes during run
OK
Cancel

Generating an Analysis Report

To generate a Diagnostic report, use the following steps:

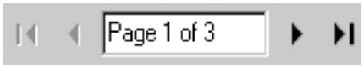
1. Open the Diagnostic run.
2. Perform the run you want to include in the report.
3. Click **Save.**

IMPORTANT: You must save the analytical run before you can create an analysis report.

4. Click **Report,** or select **Report** from the **File** menu.
   The report window opens in the work pane.

Diagnostic Report Controls for All Users

To see additional pages of the report, use the page forward and backward controls:



To change the scale of the report within the window, click one of the following buttons:

- The first button displays the report at its printed size.
- The second button fits the entire report page into the window.
- The third button fits the width of the report page into the window.
- To print the report, click **Print** at the top of the report window.

CHAPTER 6:

MAINTENANCE AND TROUBLESHOOTING

Introduction

This chapter provides step-by-step instructions for users to perform basic maintenance, troubleshooting and repair tasks on the JBAIDS instrument. Each task can be performed using tools from the tool kit that is supplied with each instrument.

The tasks performed in this chapter are the only tasks that should be performed by the operator. Do not attempt to perform any additional task without the guidance and direction of an Idaho Technology specialist. If additional repairs are needed, contact ITI General Support. If the instrument needs to be returned to ITI, refer to the steps found in Appendix B, *Instrument Return Procedures*, of this manual.

Disposal of Consumables
Dispose of all consumables in biohazardous waste Sharps containers. Be careful when handling capillaries post PCR, as broken capillaries can lead to contamination.

Before performing maintenance on the JBAIDS instrument, turn off the instrument, unplug the power and serial cables and allow the heat duct assembly to cool. Use the correct tools from the supplied tool kit and ***wear splash shield and protective gloves***.

- When working around the sample carousel, ensure that you do not bend or break the temperature sensor (see diagram in “Instrument Overview” in this chapter)
- When working inside of the instrument, ensure that you are grounded or discharged by touching the metal part on the instrument case to ensure you are not carrying any static electricity.

Deck LED Indicator Light
Located on the deck is an LED indicator light which provides the status of the instrument. Use the table below to identify the status of the instrument.

	A red light indicates that the instrument is ready to run.
	A green light indicates that the instrument is running.
	A flashing green/red light indicates that an instrument error has been detected. (Note: It is normal for the LED to flash for less than 10 seconds when the instrument is turned on.)
	The absence of a light indicates that there is no power beyond the power switch.

Hardware Troubleshooting

The following troubleshooting solutions are described in detail in this chapter.

Symptom*	Possible Solution
Instrument deck LED indicator light is blinking and unable to run	Turn the instrument off, wait 5–10 seconds, and then turn it back on. If instrument continues to blink then contact ITI Technical Support at 1-800-735-6544 or +1 (801) 736-6354.
Instrument does not turn on	Check and/or replace outlet for power Check and/or replace power cord Check and/or replace fuses (8 amps) Replace power-switch module
Chamber fan blade is broken or loose	Replace chamber fan blade
Noise, excessive or unusual, from chamber fan	Replace chamber fan motor
Noise, excessive or unusual, from case blower	Contact ITI Technical Support
Firmware reloads after every power-off	Contact ITI Technical Support
Sample tubes do not seat properly in carousel	Clean and/or replace sample carousel
A capillary has been broken in the sample carousel	Power off instrument immediately Clean/replace sample carousel Clean sample chamber
Noise from sample platter	Contact ITI Technical Support
Carousel turns with difficulty	Contact ITI Technical Support

*See Chapter 4, *JBAIDS Software,* “Maintenance: Using Self-Diagnostic Tools,” in this manual to use and perform an instrument test.

Self-Test and Diagnostic Errors

Error Message	Possible Solution
“Carousel Missing” or “Lid Open”	Ensure that the sample carousel is present and locked in position and ensure that the lid covering the sample carousel is closed (keep carousel out of direct sunlight).
“Fan Too Slow”, “Fan Too Fast” “Fan Failed”, “Fan Error”	Replace chamber fan motor
“Blower Too Slow”	Clean/replace case blower filter Replace case blower
“The following samples were not found during the seek”	Replace capillaries, make sure capillaries are properly seated, make sure sample carousel is properly seated and locked. Refer to Chapter 4, *JBAIDS Software,* “Starting the Wizard.”
All other errors	Contact ITI Technical Support at 1-800-735-6544 or +1 (801) 736-6354

Note: If the LED on the deck of the instrument continues blinking as a result of a self-diagnostic error, then power off the instrument and let it sit for 5 seconds before turning it on again.

Software Troubleshooting

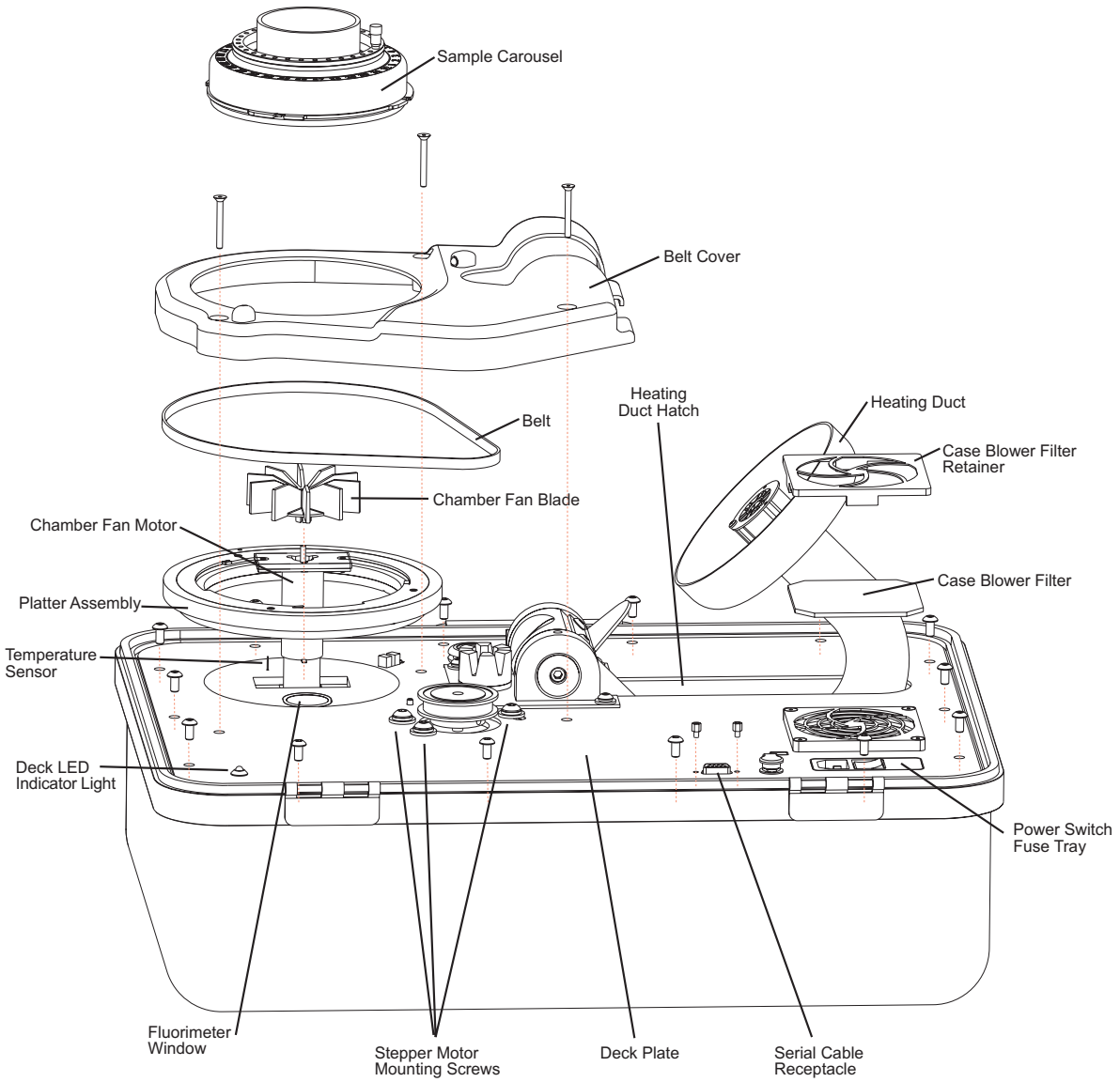
Error Message / Problem	Possible Cause / Solution
“Unable to Communicate with the Instrument”	Make sure instrument is turned on Restart the computer and software Check and/or replace serial cable Replace serial cable receptacle
“Firmware Reloading”	The instrument has detected an internal concern and is repairing itself by reloading the firmware. Do not touch the instrument or laptop while it is loading firmware.
“Unsafe Removal of Device”	You unplugged a USB device without stopping it. Unplugging devices without first stopping them can cause your computer to crash or lose valuable data. To safely unplug a USB device, use the eject/remove hardware function located on the bottom right of the screen in the Task Bar. If this is not done, drivers for USB devices may not load correctly. If drivers do not load correctly, shut down, restart the computer, and re-insert device. Do not start laptop with device in USB port.
Incorrect Date and/or Time	Upon initial setup of the JBAIDS computer, a systems administrator should log in and set the correct date and time. This can be done by clicking on the time function located on the bottom right of the screen in the Task Bar.
“Account is Locked”	See Chapter 4, *JBAIDS System Software*, “Unlocking a User Account”
Fading Computer Screen	If the screen on your computer begins to fade after normal use, it could indicate that the battery is running low. First save your work, then plug in the computer to a grounded power supply.
“Battery is Low”	When the battery begins to run low, an alert message will pop up alerting you to plug in or replace the battery. First save your work, then plug in the computer to a grounded power supply.
No Concentration Reporting	Only some assays/specimens are designed to provide concentration results. See the specific IT 1-2-3 kit instruction booklet for more information on assays / specimens.

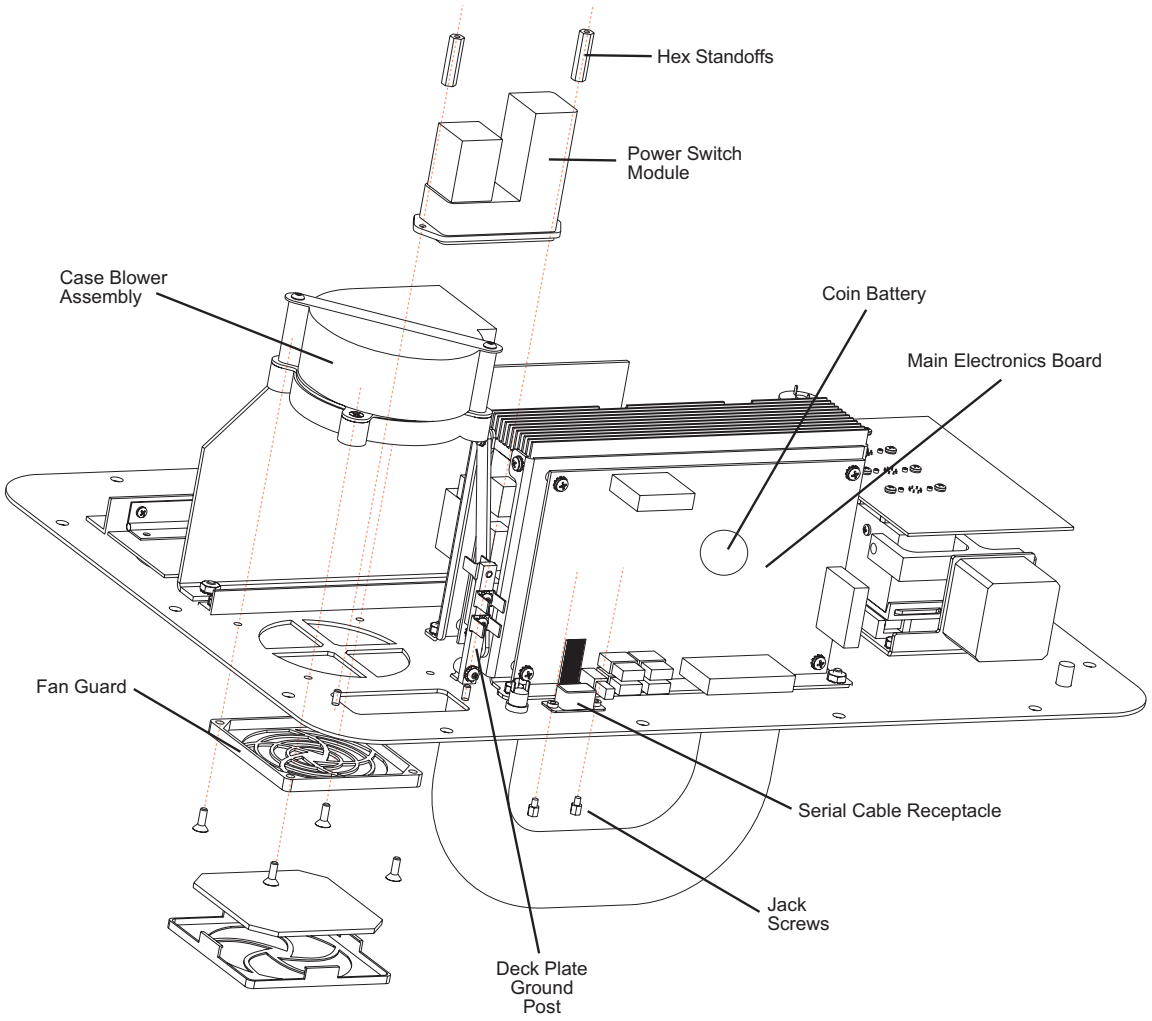
Tool Kit

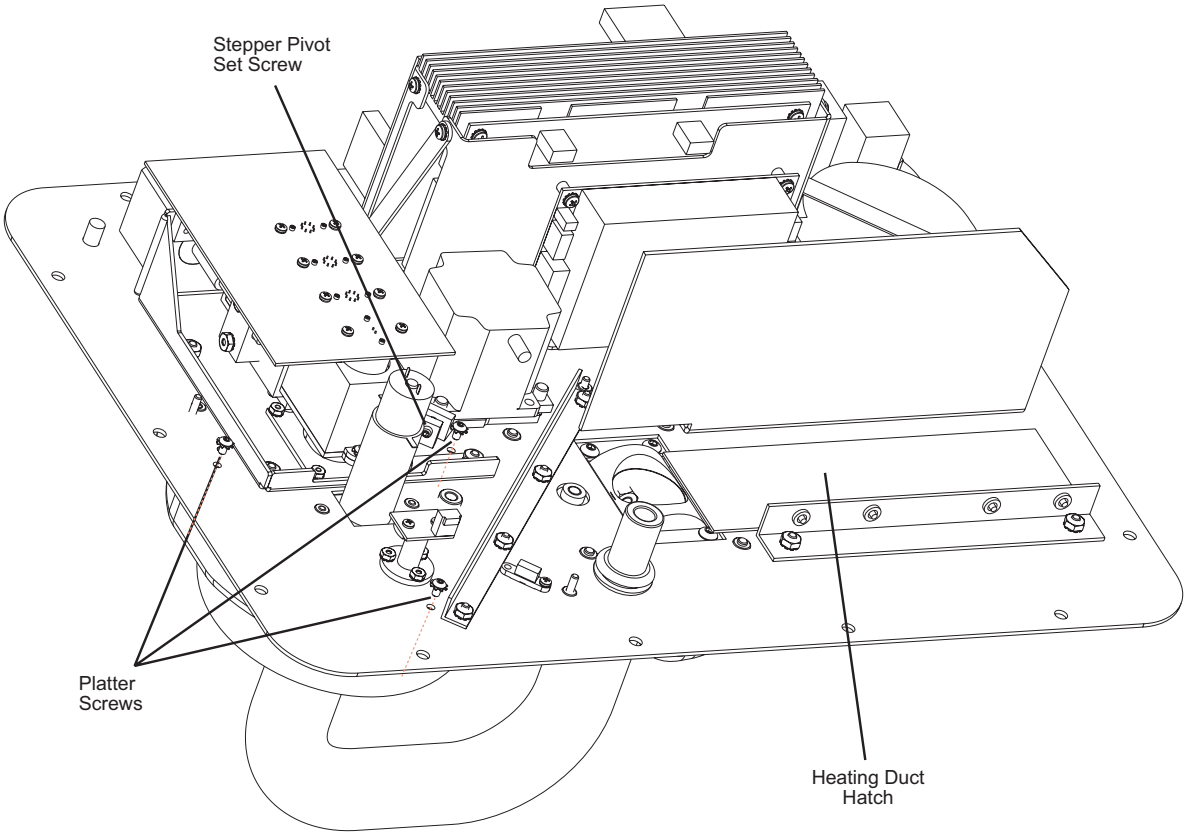
Each JBAIDS instrument comes complete with a tool kit which enables the operator to perform the tasks outlined in this manual. Use the image below to help you identify the tools needed (see Appendix E, *Instrument Parts List*). If any tool becomes damaged or lost, contact ITI General Support (1-800-736-6544) to order a replacement.

Instrument Overview

The following image provides an engineering view of the JBAIDS instrument. Use this image to familiarize yourself with the instrument.



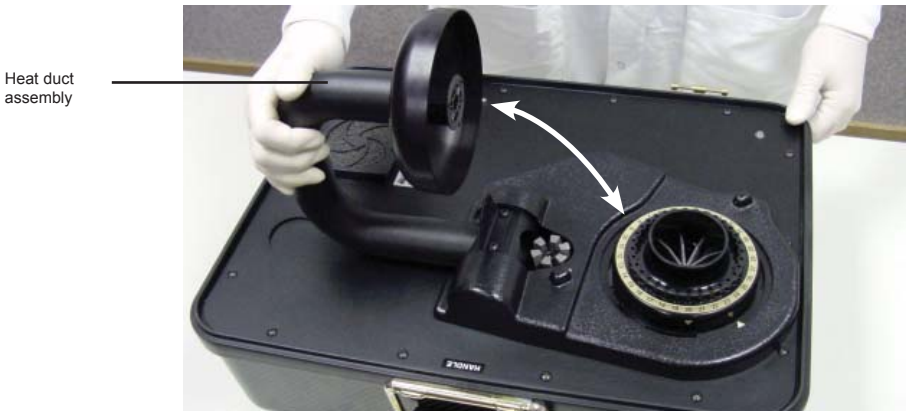

Hex Standoffs
Power Switch Module
Case Blower Assembly
Coin Battery
Main Electronics Board
Fan Guard
Serial Cable Receptacle
Jack Screws
Deck Plate Ground Post


Stepper Pivot
Set Screw
Platter
Screws
Heating Duct
Hatch

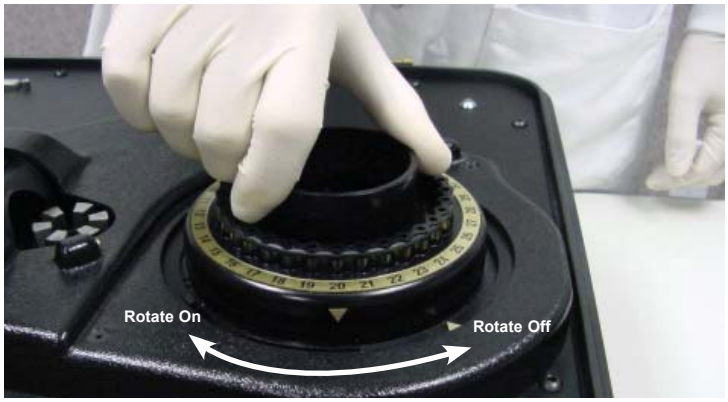
Sample Carousel Cleaning or Replacement

Type of Service:	**Preventative Maintenance / Corrective Maintenance**
Recommended Frequency:	**Every 100 hours of use**
Possible Symptoms:	**Dirty, broken capillary**
Required Parts:	**Carousel (only if replacing)**
Required Materials/Tools:	**Nylon brush (only if cleaning)** **10% bleach (1 part bleach to 9 parts water), or alternative, solution** **Lens Cleaning Solution and Cloths**
⚠ **Caution:**	**When working around the sample carousel, ensure that you do not bend or break the temperature sensor. If the sensor is bent or broken, return the instrument to ITI for repair.**

1. Turn the instrument off and unplug it from its grounded wall power source.
2. Lift the heat duct assembly to access the sample carousel.

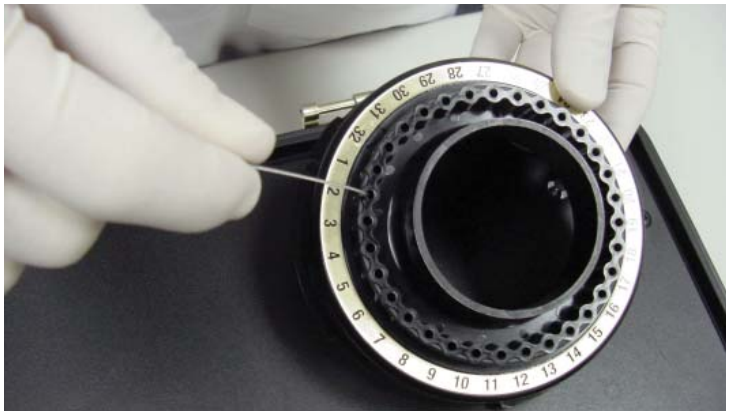


3. Remove the sample carousel from the instrument by turning it a quarter turn counterclockwise and lifting.



Note: For detailed cleaning instructions, see Chapter 2, *Safety Precautions when Working with the JBAIDS Instrument*, “Sample Carousel Decontamination.”

4. Using the specialized cleaning nylon brush, gently swab out each of the 32 sample holes in the carousel. **If replacing carousel, skip step.**



5. With the sample carousel removed, gently wipe all of the exposed surfaces around the chamber fan, sample carousel, and chamber floor with a 10% bleach (1 part bleach to 9 parts water) solution. Next, wipe down the area with distilled water to remove any contaminates.

Note: When working around the sample carousel, ensure that you do not bend or break the temperature sensor. If the sensor is bent or broken, return the instrument to ITI for repair.

Note: If refuse is caught under the chamber fan blade, follow the instructions on the following page to properly remove the chamber fan blade. Clean under the chamber fan blade and place it back into position according to the instructions on the following page.

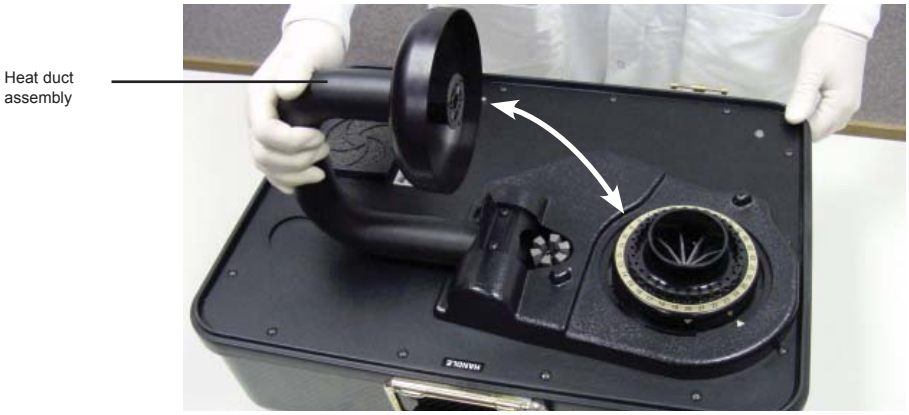
6. Clean the fluorimeter window using the lens cleaning solution and cloths.

7. Replace the sample carousel by inserting and turning it a quarter turn clockwise.

Chamber Fan Blade Replacement

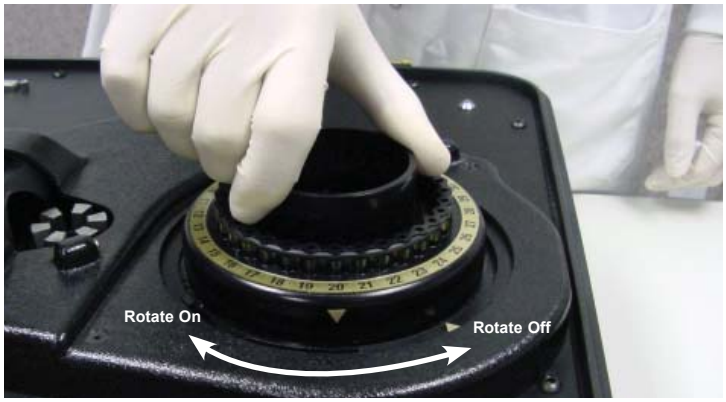
Type of Service:	**Corrective Maintenance**
Possible Symptoms:	**Physical damage (cracks, melting), blade separates from motor shaft, noise**
Required Parts:	**Chamber Fan Blade**
Required Materials/Tools:	**None**
Caution:	**When working around the sample carousel, ensure that you do not bend or break the temperature sensor. If the sensor is bent or broken, return the instrument to ITI for repair.**

1. Turn the instrument off and unplug it from its grounded wall power source.
2. Lift the heat duct assembly to access the sample carousel.



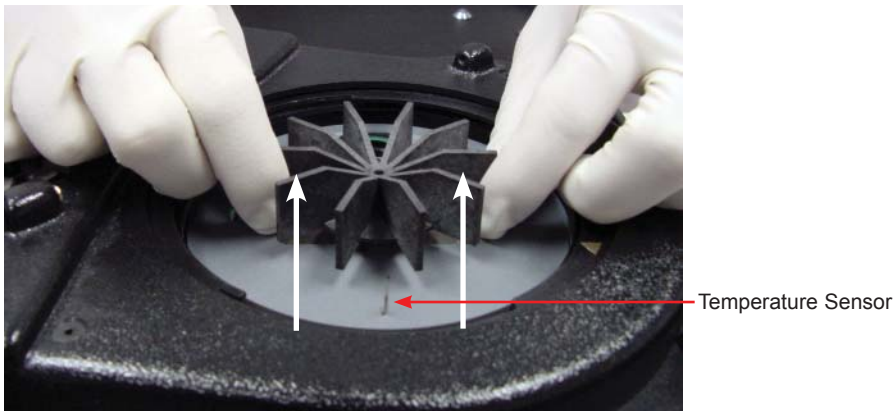
3. Remove the sample carousel from the instrument by turning it a quarter turn counterclockwise and lifting.

Note: Be careful not to hold the carousel from the bottom, or you may break any capillaries that might be in it.



4. Remove the chamber fan blade by grasping the fan blade firmly and slowly pulling up.

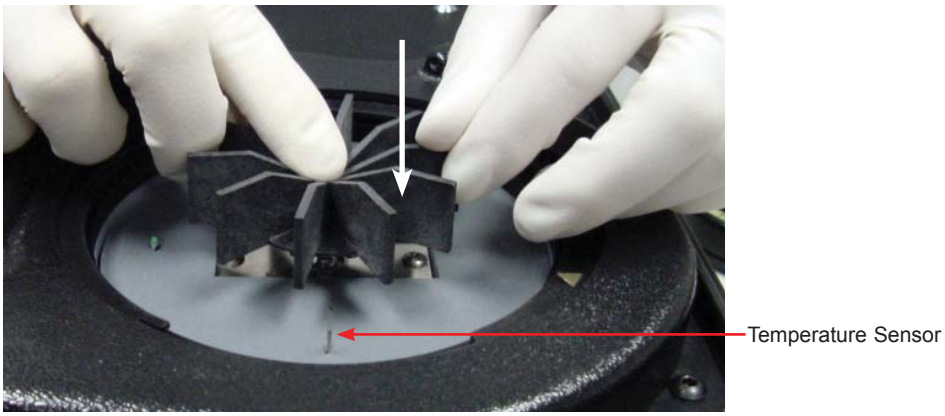
Note: When working around the sample carousel, ensure that you do not bend or break the temperature sensor. If the sensor is bent or broken, return the instrument to ITI for repair.



5. Dispose of the old fan blade.

Note: Before inserting a new fan blade, clean the chamber floor by gently wiping all of the exposed surfaces with a 10% bleach solution. Next, wipe down the area with distilled water to remove any contaminates. For detailed cleaning instructions, see Chapter 2, *Safety Precautions*.

6. Obtain a new fan blade.
7. Align the new fan blade on the motor shaft, with the shaft in line with the center hole of the fan blade, and the hub of the fan blade facing down.

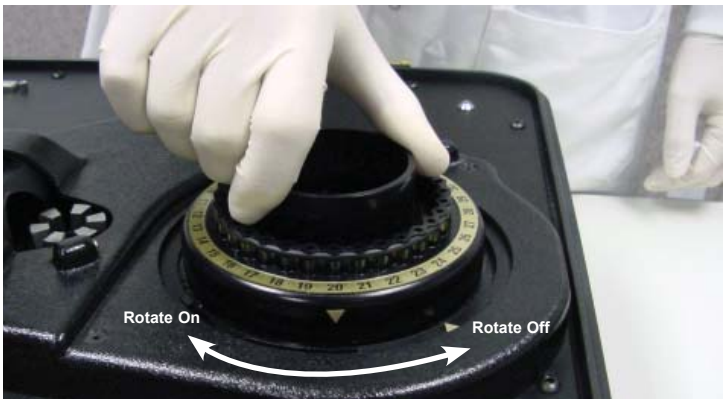


8. Press the new fan blade firmly onto the shaft until the fan blade sits against the bottom stop of the motor shaft.
9. Replace the sample carousel by inserting it and turning it a quarter turn clockwise.

Chamber Fan Motor Replacement

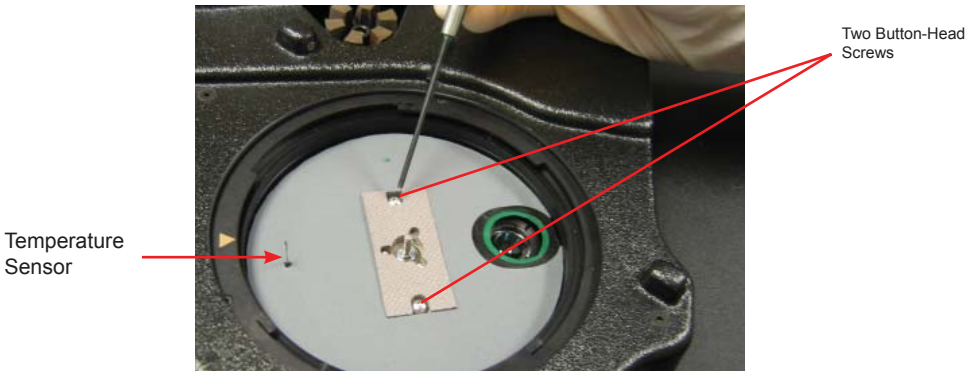
Type of Service:	**Corrective Maintenance**
Possible Symptoms:	**Excessive or unusual noise** **Self-diagnostic error:** **"Fan Too Slow"** **"Fan Too Fast"** **"Fan Failed"** **"Fan Error"**
Required Parts:	**Chamber Fan Motor Assembly**
Required Materials/Tools:	**5/64" hex driver**
⚠ **Caution:**	**When working around the sample carousel, ensure that you do not bend or break the temperature sensor. If the sensor is bent or broken, return the instrument to ITI for repair.**

1. Turn the instrument off and unplug it from its grounded wall power source.
2. Lift the heat duct assembly to access the sample carousel.
3. Remove the sample carousel by turning it a quarter turn clockwise and lifting.

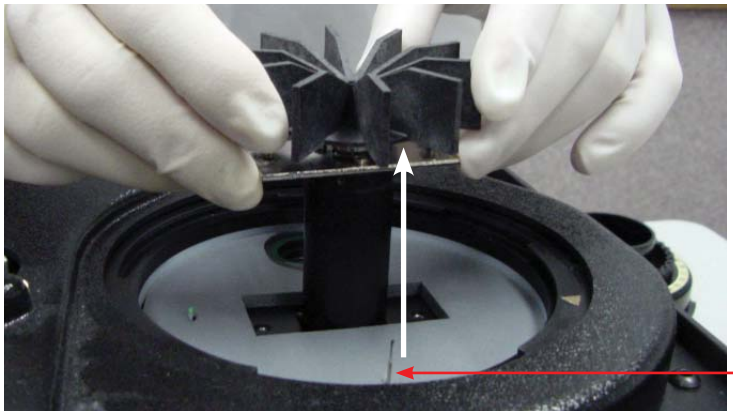


4. The fan blade may be removed for easier access to the screws (See "Chamber Fan Blade Replacement" in this chapter*)*. Remove the two button-head screws and lock washers on the fan mount plate using a 5/64" hex driver.

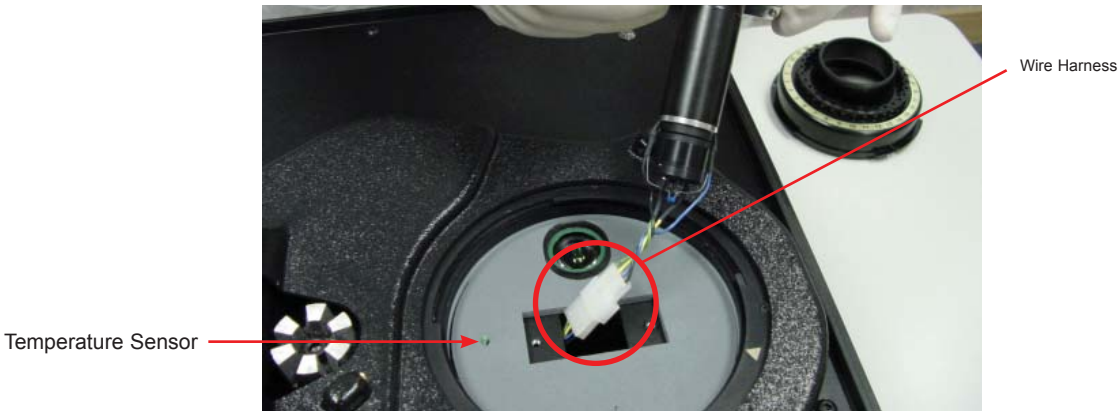
Note: When working around the sample carousel, ensure that you do not bend or break the temperature sensor. If the sensor is bent or broken, return the instrument to ITI for repair.



5. Lift the motor assembly up until the fan motor wire harness connector is above the deck plate. The connector is approximately 2 inches below the bottom of the motor.

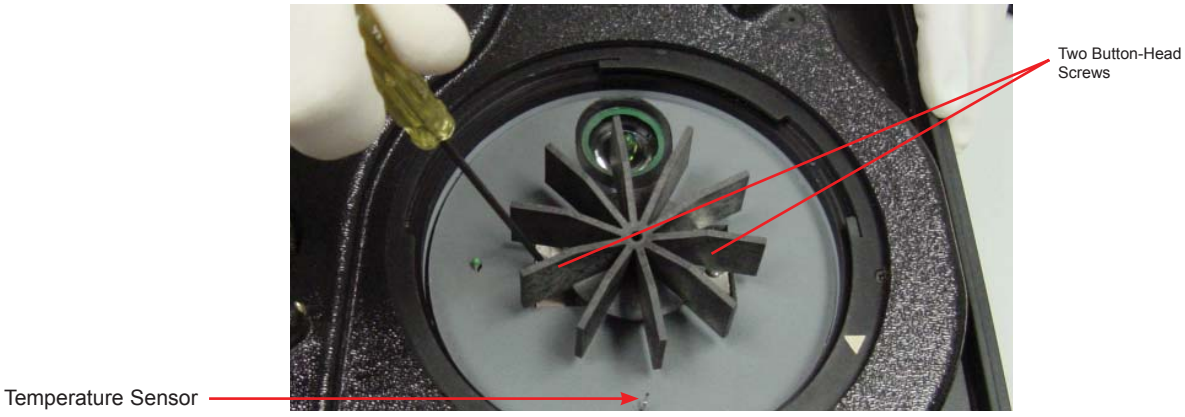


6. Disconnect the motor from the wire harness, taking care not to allow the wire harness to fall back through the deck plate.

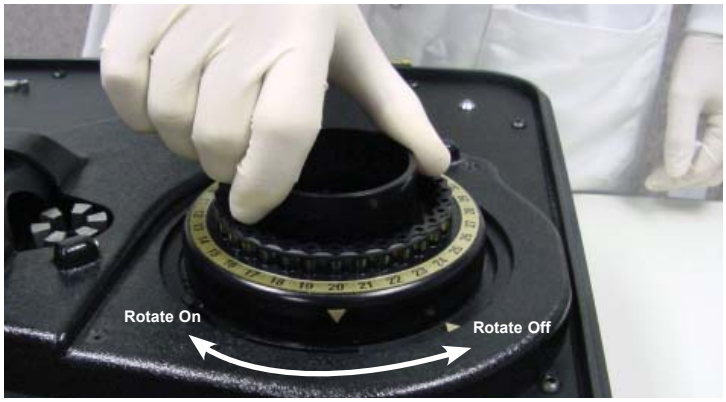


7. Dispose of the old motor assembly.
8. Connect the motor of the new chamber fan assembly to the fan motor wire harness.

9. Slide the wires and motor back through the deck plate, aligning the fan mount plate with the chamber floor foam.
10. Secure the assembly by replacing the two button head screws and lock washers.



11. Replace the sample carousel by inserting it and turning it a quarter turn clockwise.

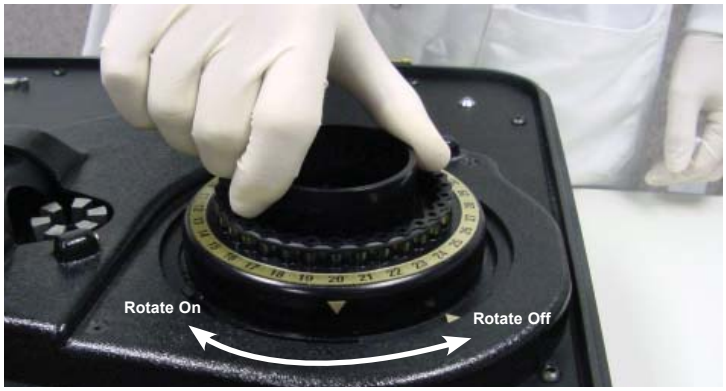


Note: You may want to run an instrument self-test to confirm that the problem has been corrected. To perform a self-test, refer to “Performing an Instrument Self-Test” in Chapter 4, *JBAIDS Software*.

Fan Motor Lubrication

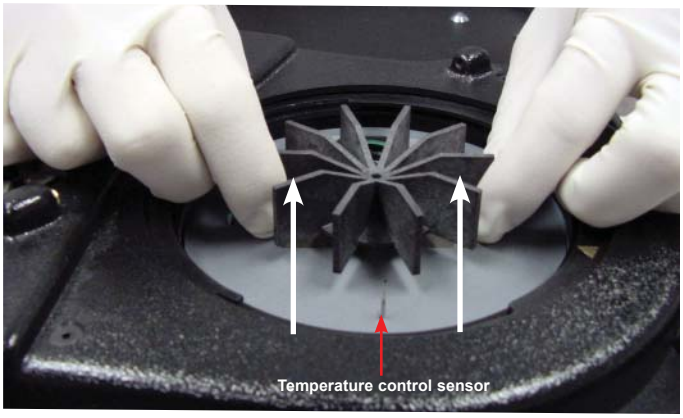
Type of Service:	**Preventative Maintenance**
Recommended Frequency:	**Every 250 hours of use**
Required Parts:	**None**
Required Materials/Tools:	**Lubricant from Tool Kit or Equivalent PTFE**
Caution:	**When working around the sample carousel, ensure that you do not bend or break the temperature sensor. If the sensor is bent or broken, return the instrument to ITI for repair.**

1. Turn the instrument off and unplug it from its grounded wall power source.
2. Lift the heat duct assembly to access the sample carousel.
3. Remove the sample carousel.

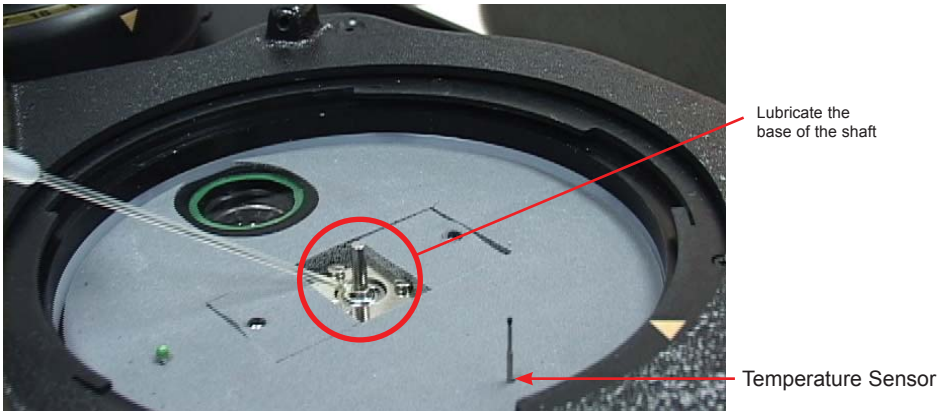


4. Remove the chamber fan blade by grasping the fan blade firmly and slowly pulling up.

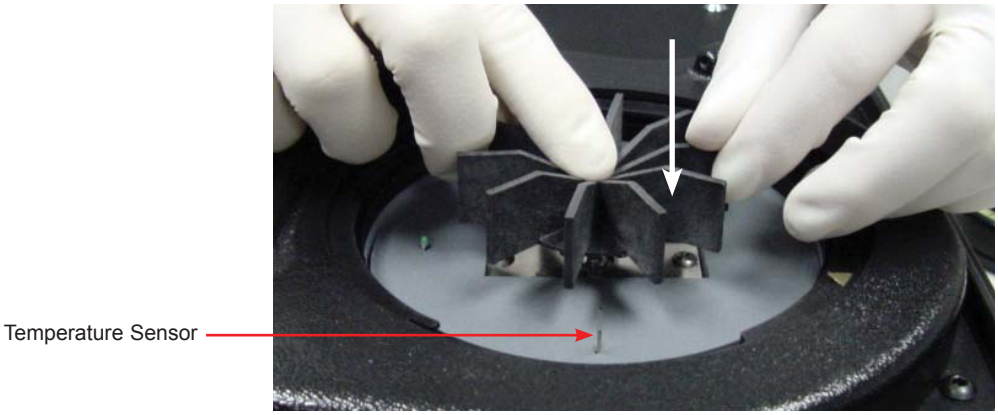
Note: When working around the sample carousel, ensure that you do not bend or break the temperature sensor. If the sensor is bent or broken, the instrument will not work properly.



5. Using the PTFE lubricant found in the tool kit, add the supplied adaptor to the tip of the bottle. Place one drop of lubricant onto the motor at the base of the shaft.



6. Replace the fan blade by aligning it on the motor shaft with the shaft in line with the center hole of the fan blade, and the hub of the fan blade facing down.
7. Press the fan blade firmly onto the shaft until the fan blade firmly sits against the bottom stop of the motor shaft.



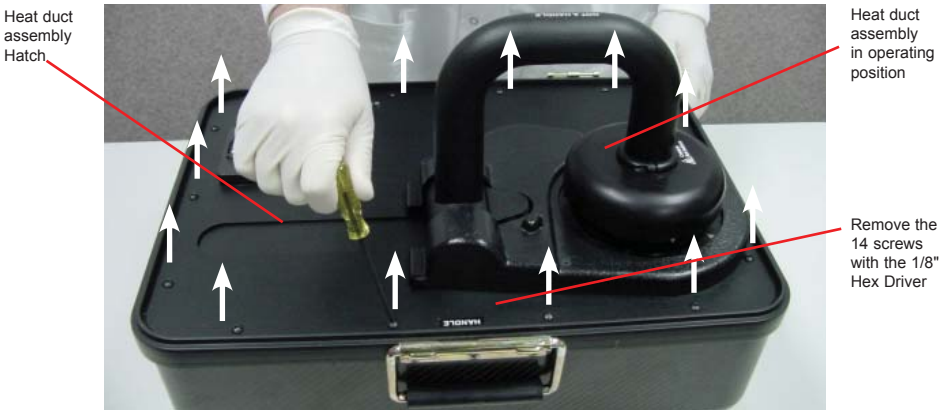
8. Replace the sample carousel by inserting it and turning it a quarter turn clockwise.

Serial Cable Receptacle Replacement

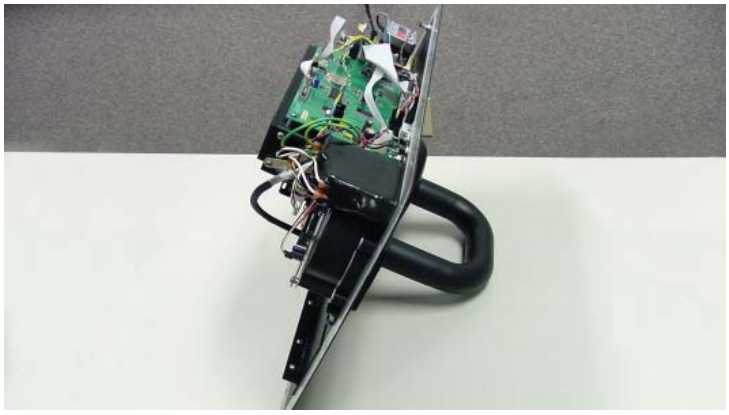
Type of Service:	**Corrective Maintenance**
Possible Symptoms:	**Self-diagnostic error message: "Unable to Communicate with the Instrument," corrosion in receptacle causing poor connection.**
Required Parts:	**Serial Receptacle/Cable**
Required Materials/ Tools:	**1/8" hex driver 3/16" nut driver**
Caution:	**This process must be done in a static free work area. Before touching the board or any of the parts the technician must make sure that they are grounded or discharged by touching the metal part of the case to ensure they are not carrying any static electricity. The static will not harm the technician, but may damage the internal electrical equipment.**

Note: First determine that the new serial cable itself is functioning, then perform this task.

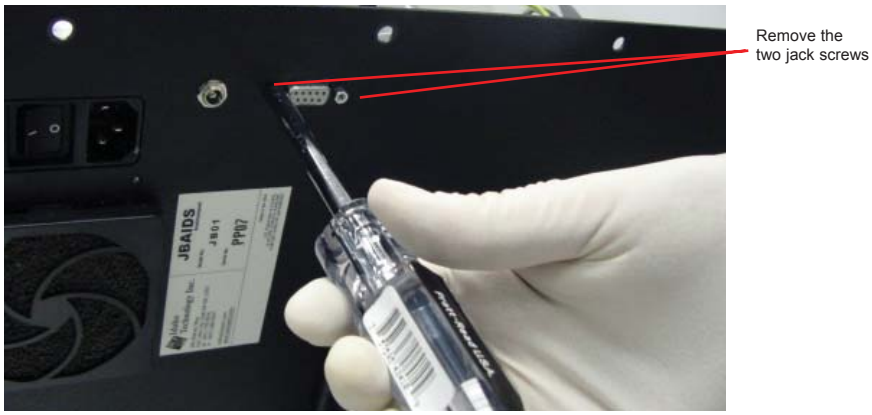
1. Turn the instrument off and unplug it from its grounded wall power source.
2. Unplug the power and serial cables from the instrument.
3. Unfasten the deck plate by removing the fourteen button head mounting screws using a 1/8" hex driver and rotate the heat duct assembly to the operating position.



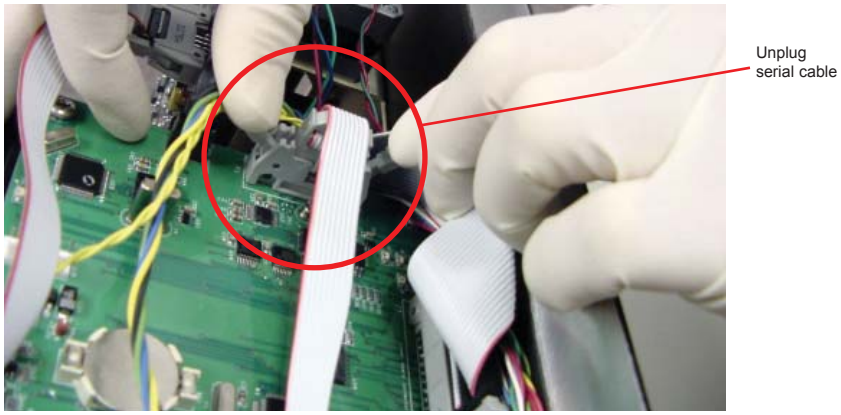
4. Using the heat duct assembly hatch, carefully lift the deck plate off of the bottom case and set it on its side on a clean surface.



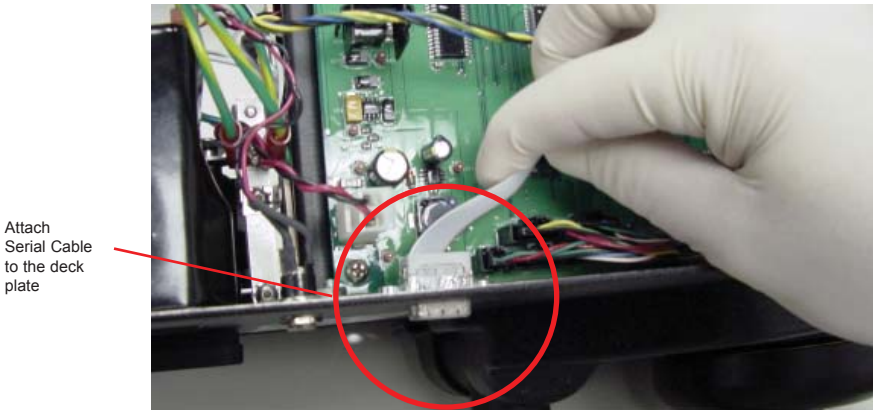
5. Remove the two jack screws from the serial plug on the deck plate using a 3/16" nut driver.



6. Unplug the serial cable from the main electronics board and set aside for proper disposal.



7. Plug the new serial cable into the main electronics board.
8. Attach the other end (DB9) of the serial cable to the deck plate using the two jack screws. Do not over tighten.



9. Carefully set the deck plate back into the bottom case by aligning the handle sticker with the handle.

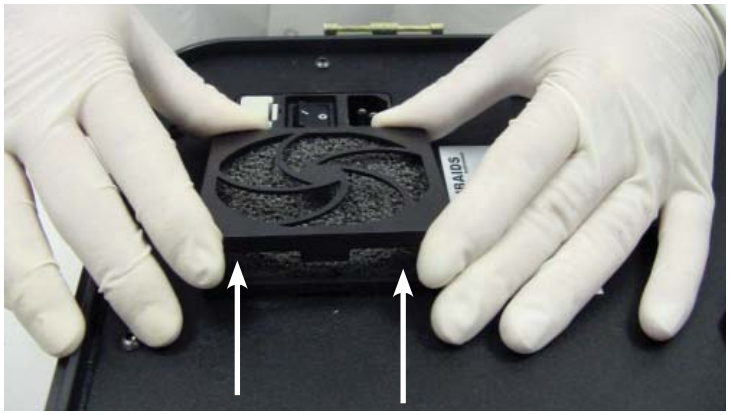
Note: Run an Instrument self-test to confirm that the problem has been corrected. To perform a self-test, refer to Chapter 4, *JBAIDS Software,* “Performing an Instrument Self-Test,” in the software section of this manual.

10. Refasten the deck plate by installing the previously removed fourteen button head mounting screws.

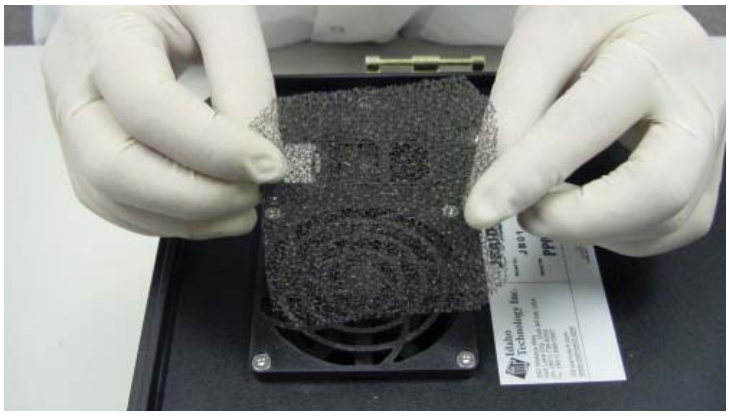
Case Blower Filter / Retainer Cleaning or Replacement

Type of Service:	**Preventative Maintenance / Corrective Maintenance**
Recommended Frequency:	**Every 100 hours of use**
Possible Symptoms:	**Dirty filter, damaged retainer, Self-diagnostic error message: "Blower Too Slow"**
Required Parts:	**Filter (only if replacing)** **Retainer (only if replacing)**
Required Materials/Tools:	**None**

1. Grasp the plastic case blower filter retainer, and remove it by gently but firmly unsnapping the four mountings (one on each side).



2. Remove the filter pad. The pad may be cleaned by rinsing it with water and allowing it to dry. Replace the filter pad onto the case blower.

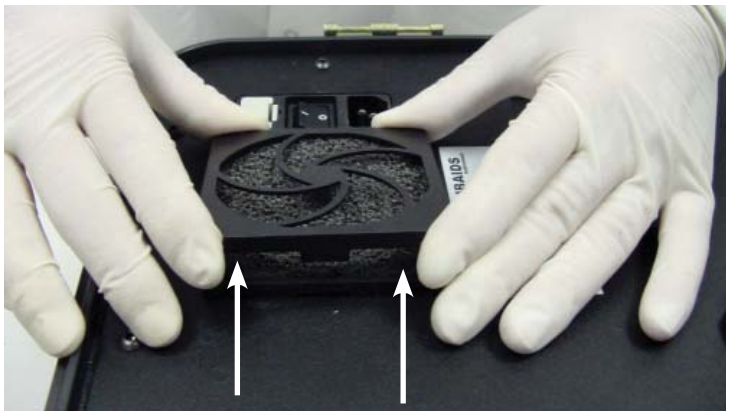


3. Snap the filter retainer back into place.

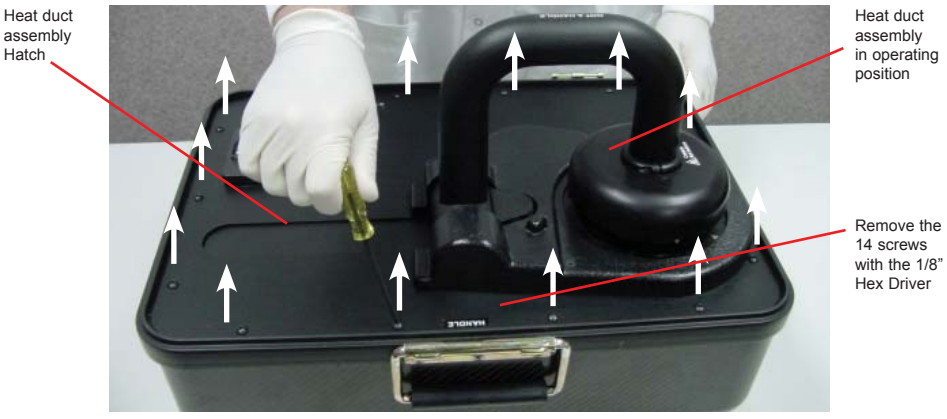
Case Blower Replacement

Type of Service:	**Corrective Maintenance**
Possible Symptoms:	**Physical damage, Noise, Self-diagnostic error message: "Blower Too Slow"**
Required Parts:	**Case Blower assembly**
Required Materials/Tools:	**5/64" hex driver, 1/8" hex driver**
⚠ **Caution:**	**This process must be done in a static free work area. Before touching the board or any of the parts the technician must make sure that they are grounded or discharged by touching the metal part of the case to ensure they are not carrying any static electricity. The static will not harm the technician, but may damage the internal electrical equipment.**

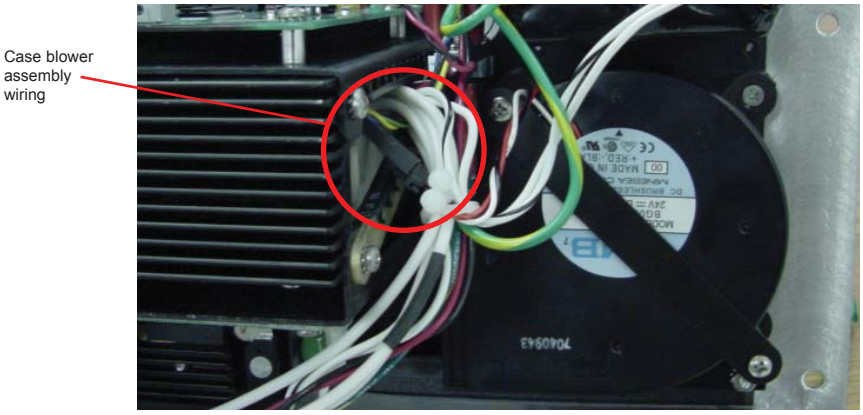
1. Turn the instrument off and unplug it from its grounded wall power source.
2. Unplug the power and serial cables from the instrument.
3. Grasp the plastic case blower filter retainer, and remove it by gently but firmly unsnapping the four mountings (one on each side). Set the retainer and filter aside for later reinstallation. (If necessary, clean or replace the filter before completing step 13.)



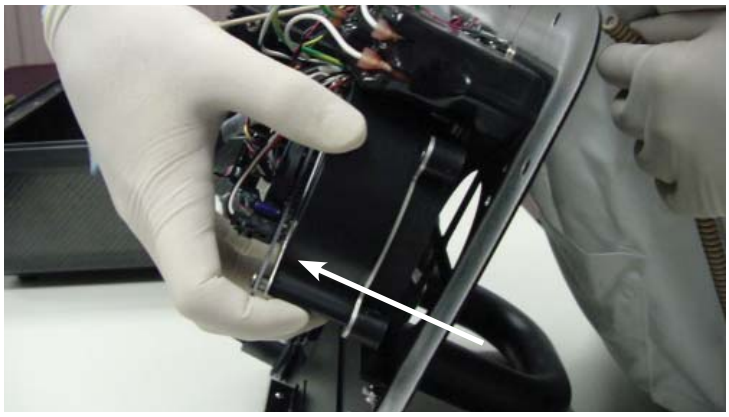
4. Unfasten the deck plate by removing the fourteen button head mounting screws using a 1/8" hex driver and rotate the heat duct assembly to the operating position.



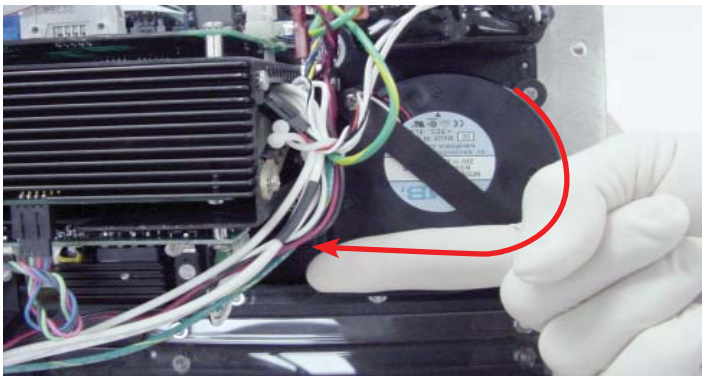
5. Using the heat duct assembly hatch, carefully lift the deck plate off of the bottom case and set it on its side on a clean surface.
6. Unplug the case blower assembly wiring.



7. Remove the case blower assembly and fan guard by using a 5/64" hex driver to remove the four flat-head screws located on the top side of the deck.



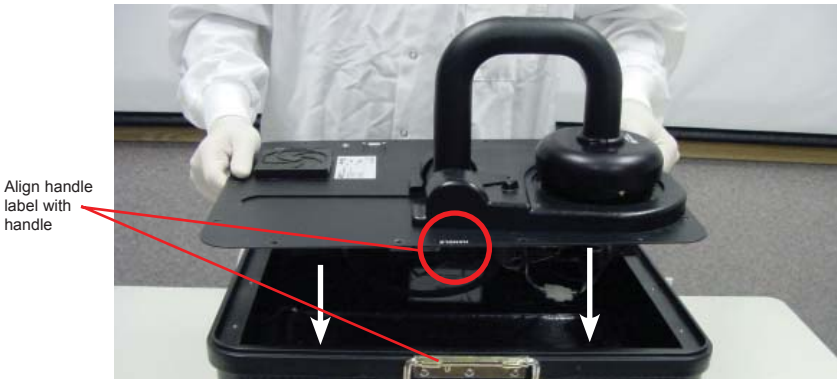
8. Obtain a new case blower assembly and insert it in the proper location, taking care to align the fan so that the outlet faces the electronics brackets as shown in the image below.



9. Fasten the assembly to the deck plate using the four flat head screws through the fan guard.

10. Re-plug the case blower wiring back together.
11. Carefully set the deck plate back into the bottom case by aligning the handle label with the handle.

Note: Run an Instrument self-test to confirm that the problem has been corrected. To perform a self-test, refer to Chapter 4, *JBAIDS Software,* “Performing an Instrument Self-Test,” in the software section of this manual.

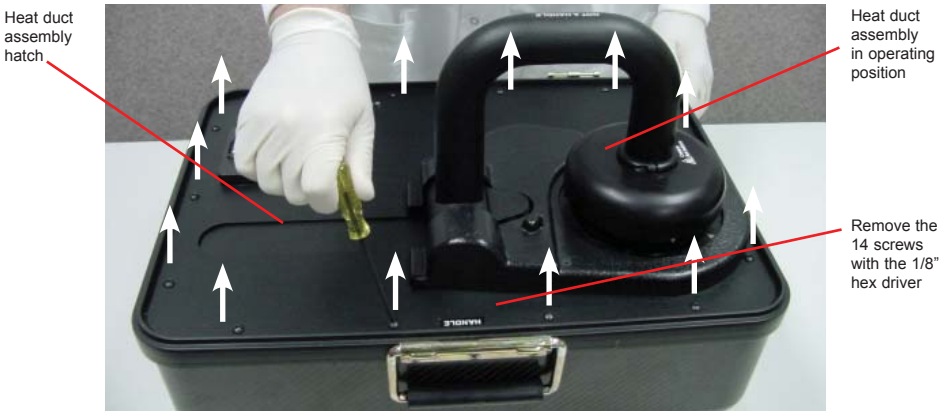


12. Refasten the deck plate by installing the previously removed 14 button head mounting screws.
13. Replace the case blower filter and filter cover.

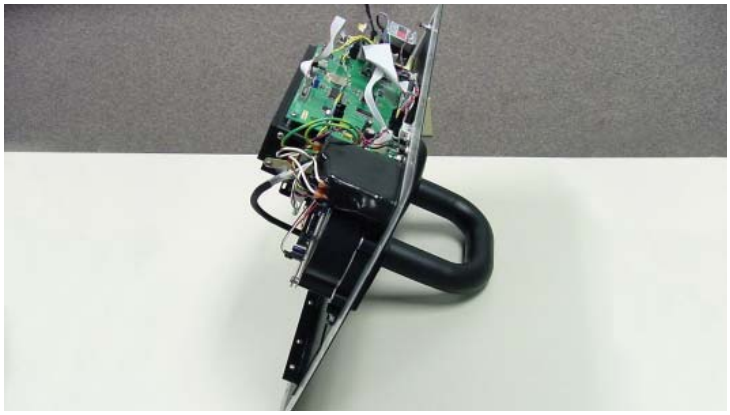
3V Lithium Coin Battery Replacement

Type of Service:	**Preventative Maintenance/Corrective Maintenance**
Recommended Frequency:	**3 years**
Possible Symptoms:	**Must reload firmware after every power off**
Required Parts:	**Battery**
Required Materials/Tools:	**1/8" hex driver**
Caution:	**This process must be done in a static free work area. Before touching the board or any of the parts the technician must make sure that they are grounded or discharged by touching the metal part of the case to ensure they are not carrying any static electricity. The static will not harm the technician, but may damage the internal electrical equipment.**

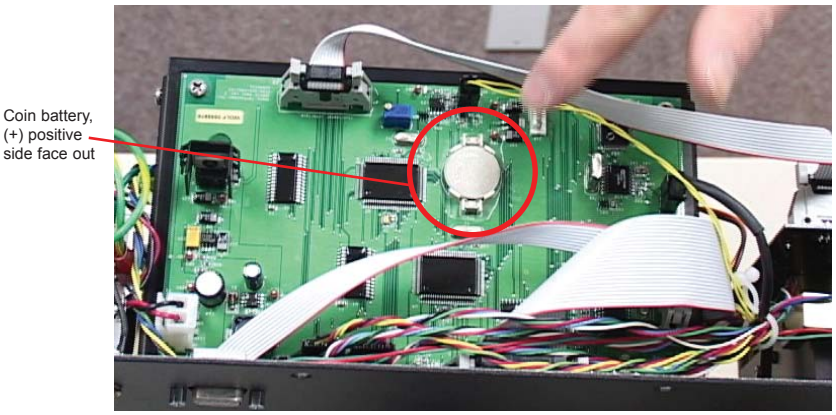
1. Turn the instrument off and unplug it from its grounded wall power source.
2. Unplug the power and serial cables from the instrument.
3. Unfasten the deck plate by removing the 14 button head mounting screws using a 1/8" hex driver and rotate the heat duct assembly to the operating position.



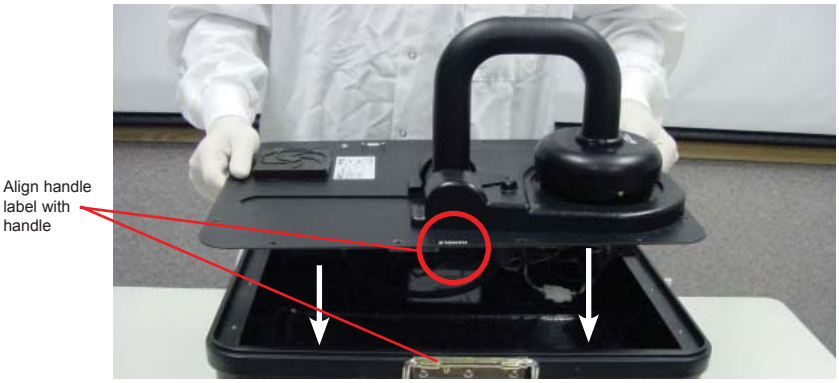
4. Using the heat duct assembly hatch, carefully lift the deck plate off of the bottom case and set it on its side on a clean surface.



5. Locate the coin battery on the side of the power board.



6. Using fingertips, remove the coin battery and dispose in appropriate lithium battery disposal location.
7. Obtain a new battery and insert in the battery holder, snapping it in place with firm finger pressure, with the positive (+) side of the battery facing out.
8. Carefully set the deck plate back into the bottom case by aligning the handle label with the handle.

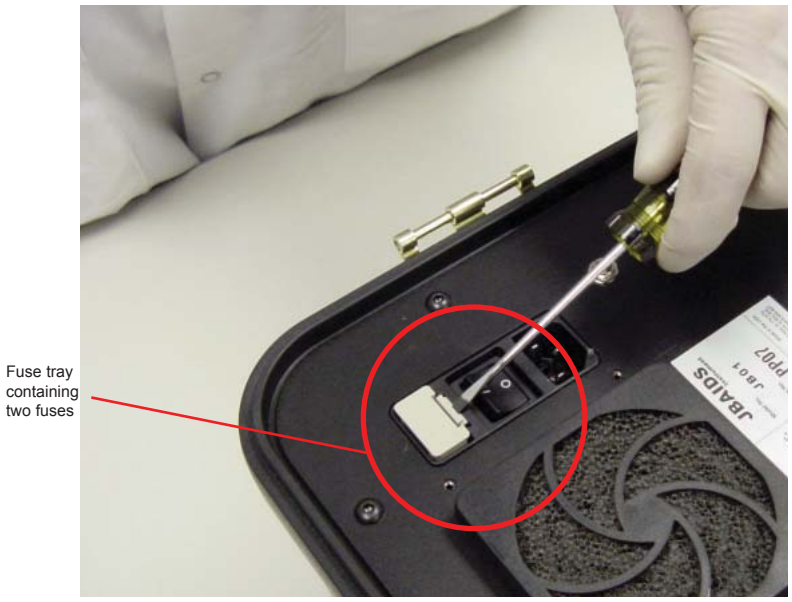


9. Refasten the deck plate by installing the previously removed fourteen button head mounting screws.

Power Switch Fuse Replacement

Type of Service:	**Corrective Maintenance**
Possible Symptoms:	**No power (deck LED indicator light does not turn on)**
Required Parts:	**Fuses**
Required Materials/Tools:	**Small flat-head screw driver**
⚠ **Caution:**	**USE ONLY 8-amp, 250-volt rated fuses. If incorrect fuses are used, it could damage the electrical components of the instrument.**

1. Unplug the instrument from the grounded power source.
2. Unplug the power and serial cables from the instrument.
3. The fuse tray is located next to the power switch. Place a small flat-head screwdriver in the small slot to pop the fuse tray out of the mounting hole. The fuse tray will pop up when the plastic latch is released.

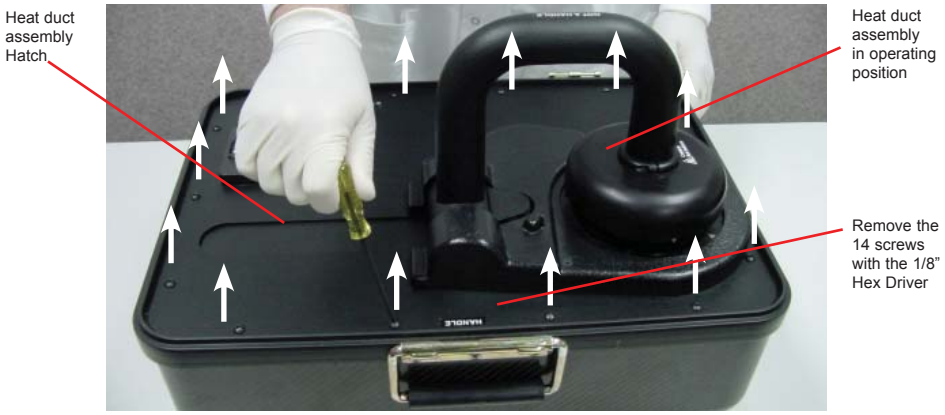


4. Remove the fuses from the fuse tray and discard the broken fuse(s).
5. Place the new fuses into the fuse tray, either direction will do.
6. Insert the fuse tray back into the mounting location, and press down to snap it into place.
7. Plug the instrument back in to the grounded power source and turn the instrument on to ensure that it works properly. Test the power switch to verify that the LED is lit.

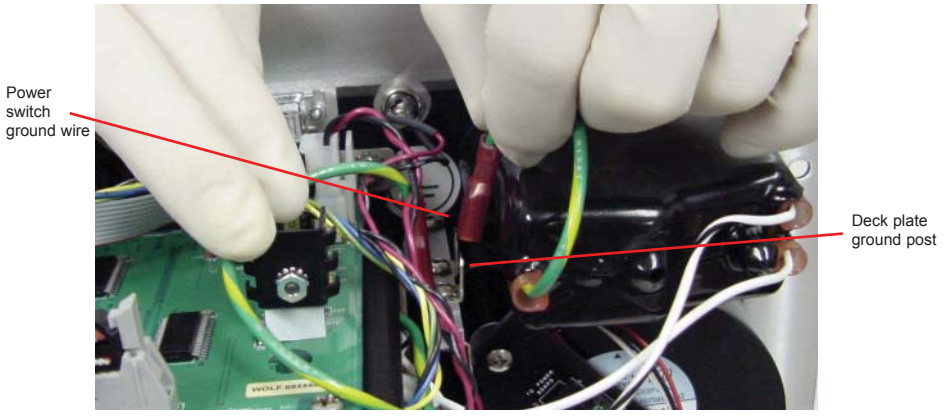
Power Switch Module Replacement

Type of Service:	**Corrective Maintenance**
Possible Symptoms:	**No power due to discontinuity through switch**
Required Parts:	**Power Switch Module**
Required Materials/Tools:	**1/8" hex driver, ¼" nut driver, LockTite™ thread locker or equivalent**
⚠ **Caution:**	**This process must be done in a static free work area. Before touching the board or any of the parts the technician must make sure that they are grounded or discharged by touching the metal part of the case to ensure they are not carrying any static electricity. The static will not harm the technician, but may damage the internal electrical equipment.**

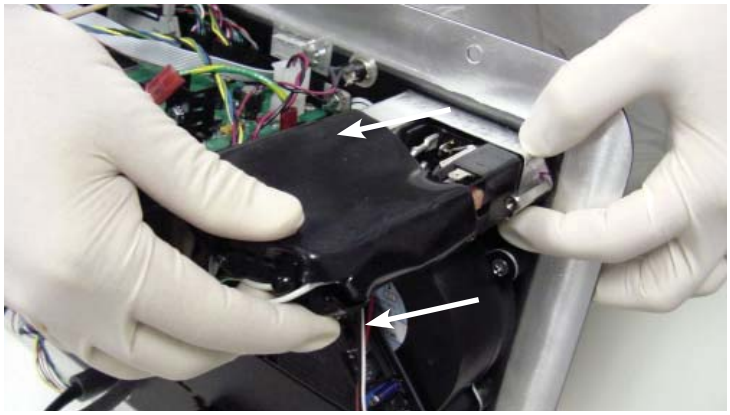
1. Turn the instrument off and unplug it from its grounded wall power source.
2. Unplug the power and serial cables from the instrument.
3. Unfasten the deck plate by removing the fourteen button head mounting screws using a 1/8" hex driver and rotate the heat duct assembly to the operating position.

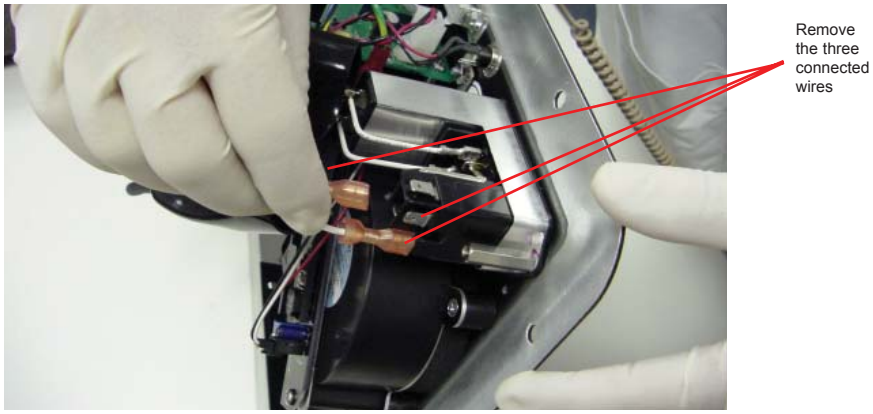


4. Using the heat duct assembly hatch, carefully lift the deck plate off of the bottom case and set it on its side on a clean surface.
5. Remove the power switch ground wire (green/yellow) from the deck plate ground post by pulling the connector off of the tab on the ground post.

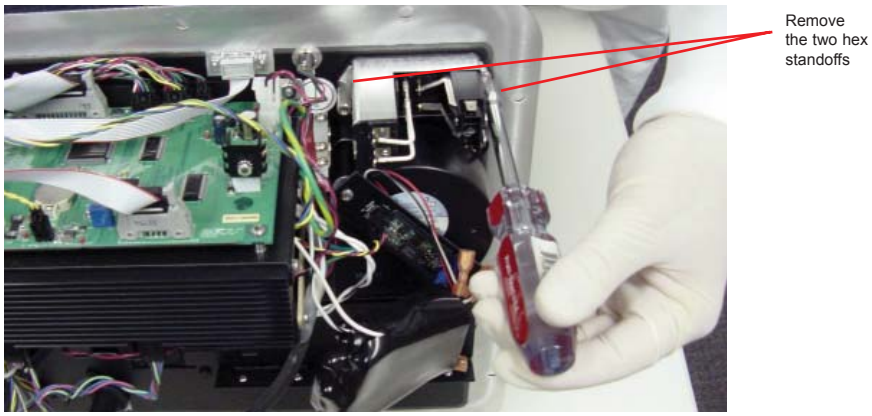


6. Slide the rubber boot off of the power switch module, and remove (unplug) the three wires connected to the module by pulling each off of its tab.



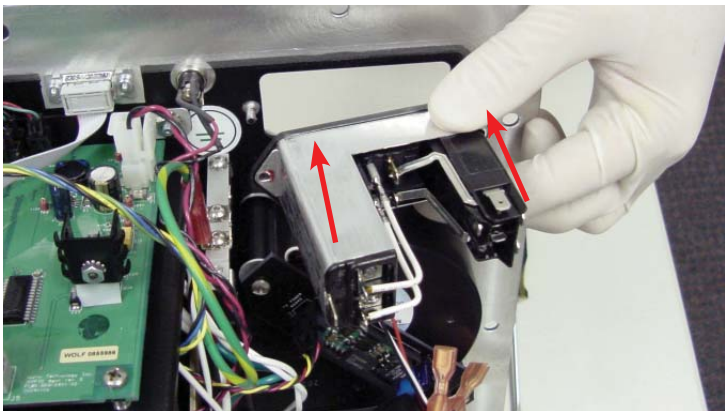


7. Remove the two 1" hex standoffs holding the module in place using a ¼" nut driver.

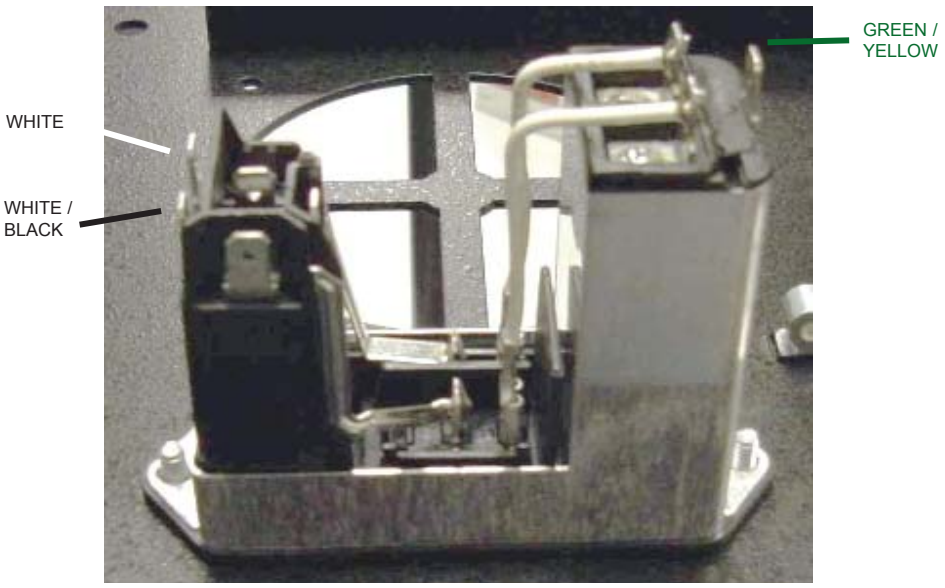


8. Remove the module and remove the fuses from the top of the switch for future use.

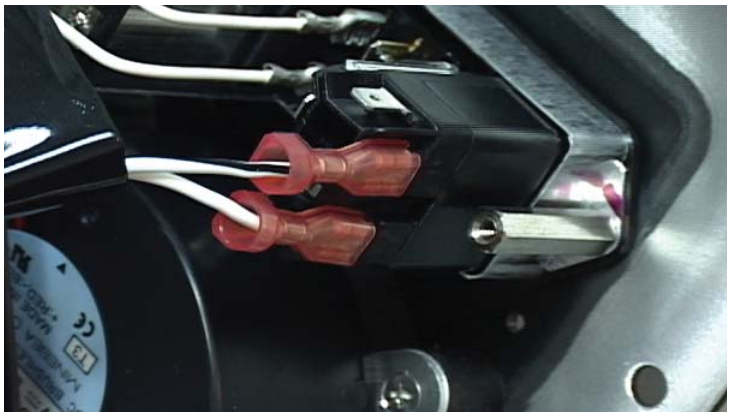
9. Obtain a replacement power switch module and place it into position. Apply thread locker to the two threaded studs and tighten the hex standoffs onto them, securing the module.



10. Re-attach (re-plug) the three wires to the module as shown below.



11. Slide the boot back down over the wires and module.
12. Re-attach the power switch ground wire to the deck plate ground post.



13. Carefully set the deck plate back into the bottom case by aligning the handle label with the handle.
14. Remove the fuse tray from the replaced power switch module and insert it into the new power switch module.
15. Test the power switch by plugging in the power cord and turning it on to verify that the LED is lit.
16. Refasten the deck plate by installing the previously removed fourteen button head mounting screws.

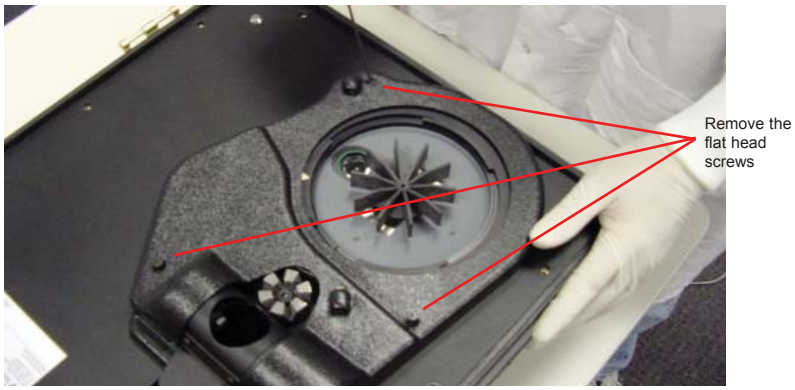
Platter Cleaning

Type of Service:	**Preventative Maintenance**
Recommended Frequency:	**Every 3000 hours use**
Possible Symptoms:	**Carousel turns with difficulty**
Required Parts:	**None**
Required Materials/Tools:	**5/64" hex driver, 5/32" hex driver 1/8" hex driver, 3/32" hex driver Phillips screwdriver 10% bleach solution LockTite thread locker or equivalent**
Caution:	**This process must be done in a static free work area. Before touching the board or any of the parts the technician must make sure that they are grounded or discharged by touching the metal part of the case to ensure they are not carrying any static electricity. The static will not harm the technician, but may damage the internal electrical equipment.**

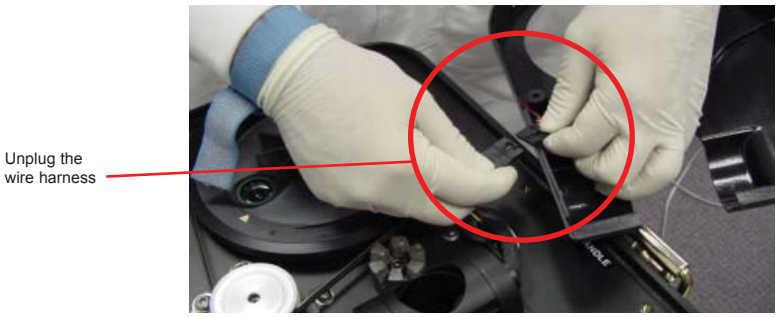
1. Turn the instrument off, unplug the power and serial cables from the instrument.
2. Remove the sample carousel.

Note: When working around the sample carousel, ensure that you do not bend or break the temperature sensor. If the sensor is bent or broken, the instrument will not work properly.

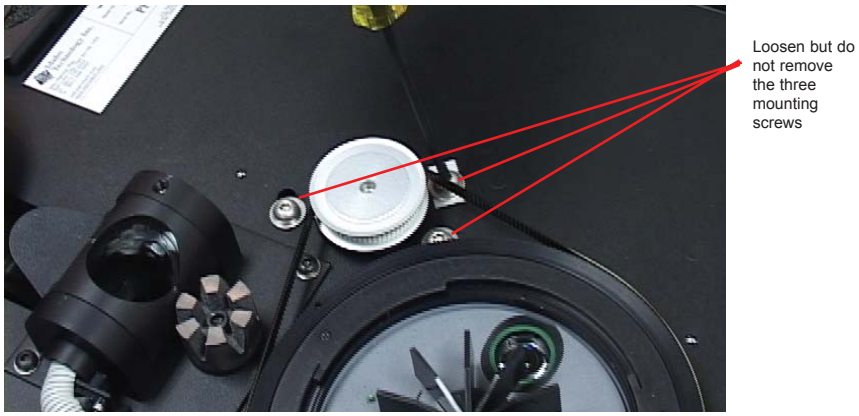
3. Unfasten the three flat head screws on the plastic belt cover using a 5/64" hex driver.



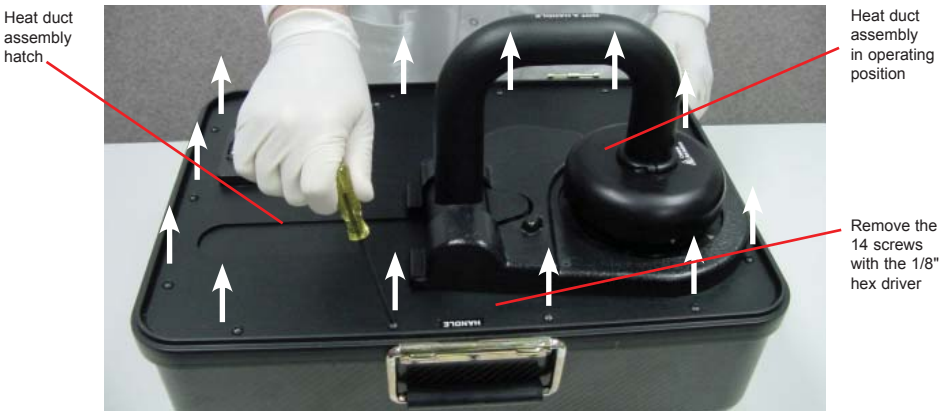
4. Unplug the belt cover wire harness and remove the belt cover.



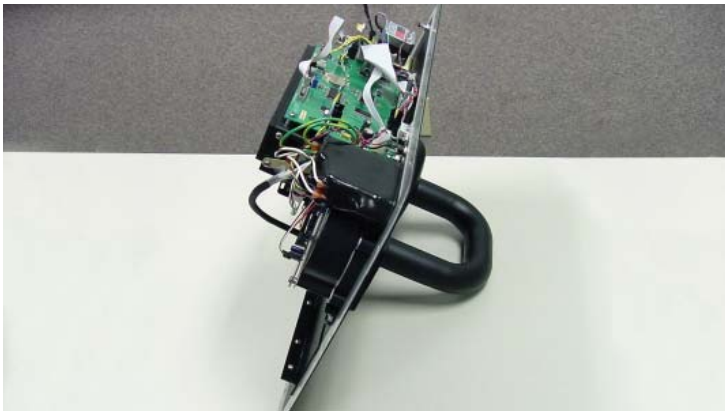
5. Loosen, ***but do not remove***, the three stepper-motor mounting screws using a 5/32" hex driver.



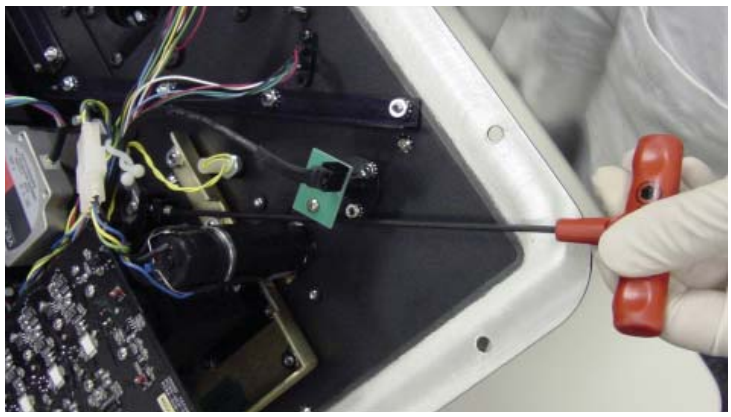
6. Unfasten the deck plate by removing the 14 button head mounting screws using a 1/8" hex driver and rotate the heat duct assembly to the operating position.



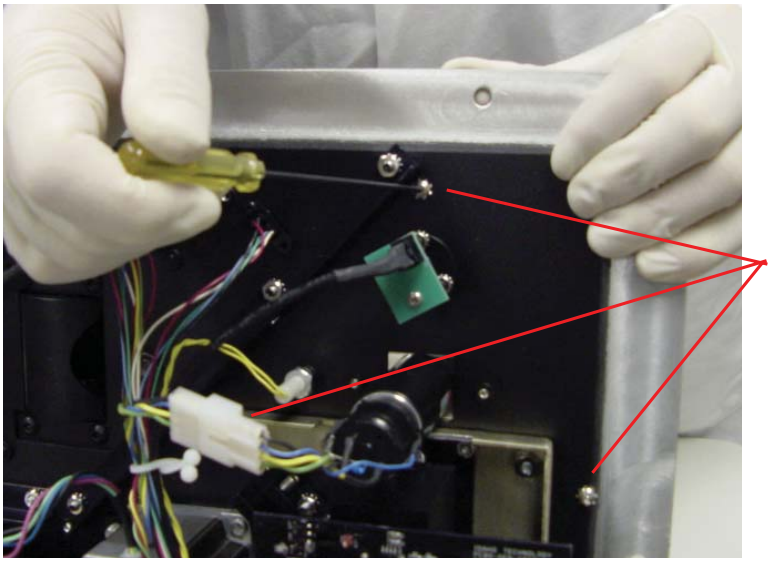
7. Using the heat duct assembly hatch, carefully lift the deck plate off of the bottom case and set it on its side on a clean surface. The deck plate can also be placed upsidedown into the case for convenience.



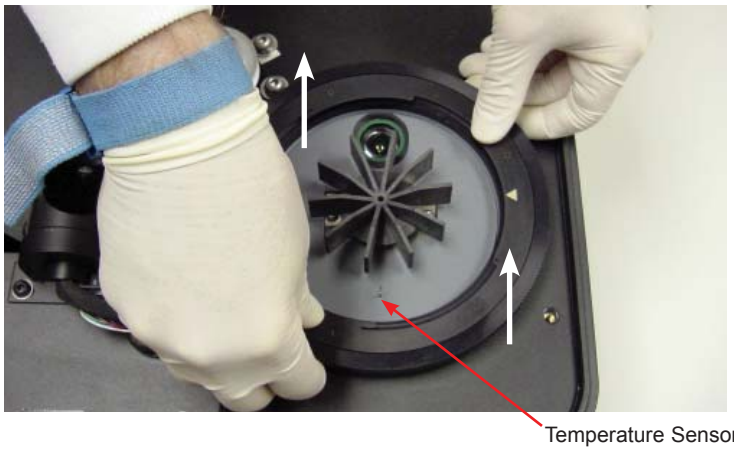
8. **CAUTION: Care must be taken in this step to rotate the set screw the number of turns indicated, as the same number of turns will be used to retension the belt after cleaning.** Using a 3/32" hex driver, back out the stepper pivot set screw by turning it counterclockwise **three complete (360º) turns.** The tension on the toothed belt will then be low enough to remove the belt. However, **do not remove the belt**; it is not removed until step 10.



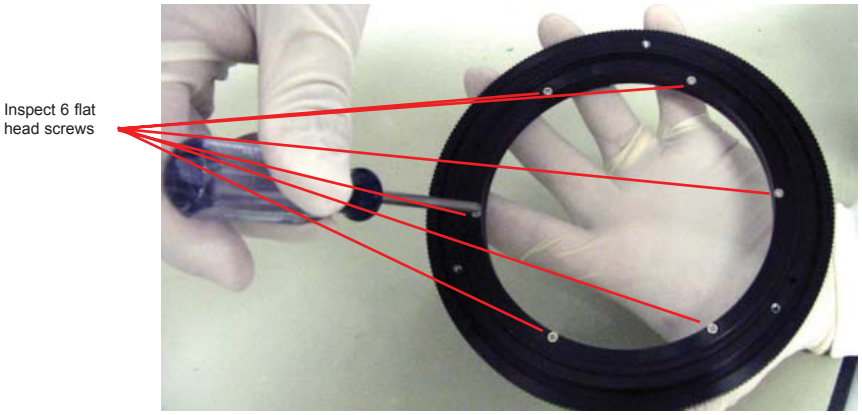
9. Remove the three button head screws and washers that hold the platter assembly onto the deck plate using a 5/64" hex driver. Rotate the deck plate to its upward position and set it back into the case.



10. Remove the platter assembly by lifting it off the two pins in the deck plate. The lower outside ring will separate from the remaining platter assembly components.



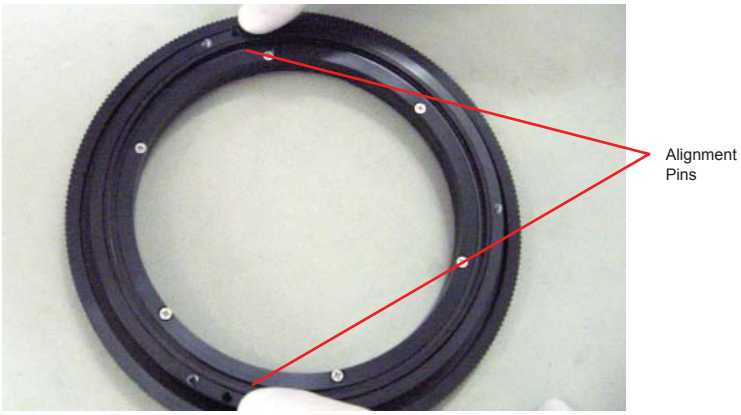
11. Clean the platter assembly and lower outside ring with 10% bleach solution. Follow the bleach solution with a wipe down with distilled water to remove any contaminants.
12. Inspect the six flat head screws holding the platter assembly together. If any are loose, add a small amount of thread locker and retighten with a Phillips screwdriver, taking care not to get any thread locker into the bearing.



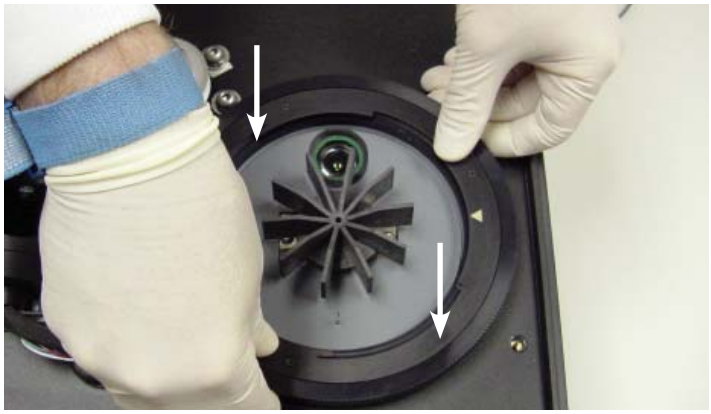
13. Clean the deck plate around the chamber floor foam with a 10% bleach solution. Follow the bleach solution with a wipe down of the area with distilled water to remove any contaminates.

14. Replace the platter assembly and lower outside ring onto the two pins in the deck plate.

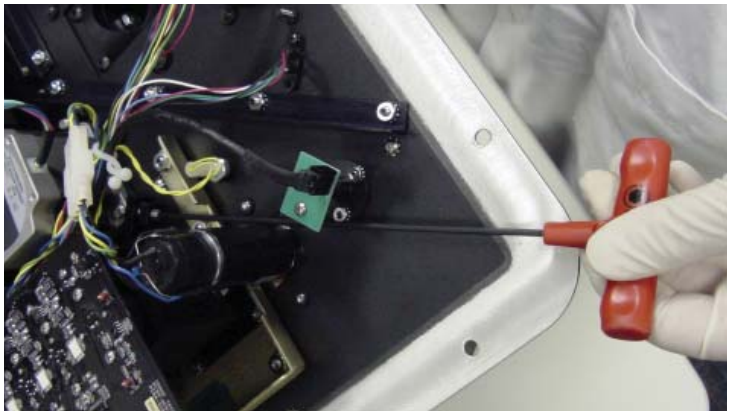
Note: Notice that there are five total holes located around the platter assembly. Two of them are not threaded, these are the pin alignment holes and the remaining three are threaded for the screws.



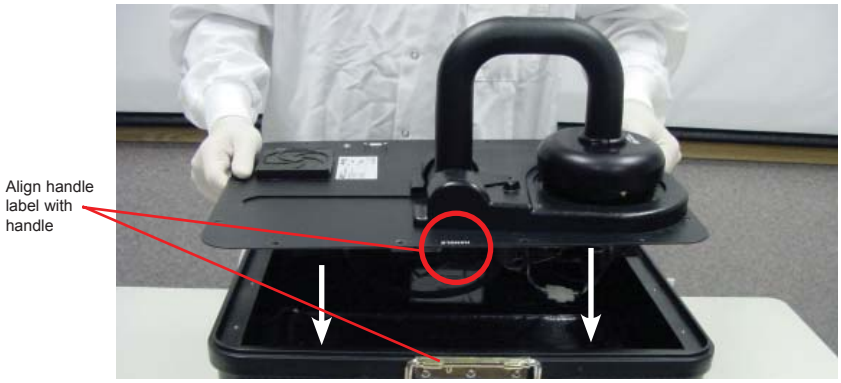
15. Secure the platter assembly to the deck plate with the 5/64" hex driver using the three button head screws and washers. Tighten the screws making sure not to bind the lower outside ring. When assembled, the carousel should rotate smoothly and freely.
16. Place the toothed belt around the gear pulley on the carousel stepper motor and then around the geared teeth of the drive ring. If the belt does not fit, pivot the stepper motor so that it is closer to the drive ring.



17. With the toothed belt in place, tension the belt by turning the stepper pivot set screw clockwise **three complete (360º) turns**, thus pivoting the motor away from the drive ring and tensioning the belt. Be sure that the teeth in the belt mesh properly with the teeth of the geared drive ring. Turning the geared ring helps to mesh the teeth correctly.



18. Tighten the three stepper motor mounting screws.
19. Reconnect the belt cover wire harness. Replace and secure the belt cover with the three flat head screws.
20. Carefully set the deck plate back into the bottom case by aligning the handle label with the handle.
21. Run an instrument self-test to confirm that the problem has been corrected. To perform a self-test, refer to Chapter 4, *JBAIDS Software,* “Performing an Instrument Self-Test,” in the software section of this manual.



22. Refasten the deck plate by installing the previously removed 14 button head mounting screws.
23. Replace the sample carousel by inserting it and turning it a quarter turn clockwise.

APPENDIX A:

FLUORIMETRIC REAL-TIME DETECTION PRINCIPLES

Polymerase Chain Reaction Basics

Polymerase chain reaction (PCR), also called amplification, is the process of making billions of copies of nucleic acid. This process involves separating the double-stranded deoxyribose nucleic acid (DNA) into separate strands and making multiple copies of each strand. A large quantity of DNA is needed for recordable fluorescence.

To copy DNA, three components are needed: 1) DNA polymerase; 2) a supply of the four nucleotide bases—deoxyribonucleotide triphosphate or dNTPs; and 3) primers. DNA polymerases, whether from humans, bacteria, or viruses, cannot copy a chain of DNA without a short sequence of nucleotides to “prime” the process. This stretch of DNA is called a primer. Once the primer anneals, DNA polymerase can take over making the rest of the new chain.

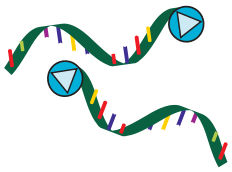
Real-time PCR is a complex mixture of sample DNA, primers, probes, dNTP molecules, DNA polymerase enzyme, and buffer. The PCR reaction is incorporated with either nonspecific DNA binding dyes or a fluorescent-based probe system to monitor the amplification of DNA during the temperature cycling.

Sample DNA

- Provides the target template.

Primer

- Consists of a short segment of nucleotides
- Defines the sequence of DNA to be amplified
- Complements a specific DNA target
- Anneals to single-stranded DNA template
- Acts as a docking station for DNA polymerase



Probes

- DNA specific, fluorescent dyes attached
- Approximately 25 bases long
- Fluorescence is proximity dependent
- Fluorescence proportional to PCR product generated
- Hydrolysis—one probe
  - 5' reporter fluorophore
  - 3' quencher
  - Fluorophore cleaved by Taq resulting in fluorescence
- Hybridization—two probes, fluorescence resonance energy transfer (FRET)
  - Annealing of two probes next to each other leads to increase in fluorescence
  - one sensor probe, 3' fluorophore
  - one anchor probe, 5' fluorophore

dNTPs

• dNTP nucleotide bases are building blocks used for DNA synthesis
• Equal amounts of nucleotides are used to prevent mismatched bases

Taq

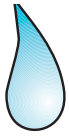
• Enzyme isolated from thermophilic *Thermus aquaticus*
• Builds a DNA copy by placing each nucleotide base in its proper position.
• Uses a template strand of DNA for copying
• Has 5' exonuclease activity

Buffer

• Maintains optimal pH for PCR
• PCR requires $MgCl_2$; Mg^{2+} binds to dNTPs and to DNA
• DNA polymerase requires free Mg^{2+} for activity

Water

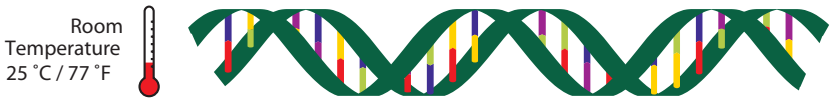
The universal diluent



Polymerase Chain Reaction

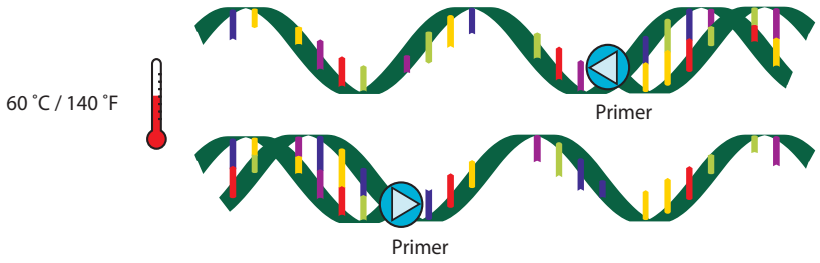
The three parts of PCR are carried out in the same vial, but at different temperatures. Each PCR cycle is comprised of three processes: denaturation, primer annealing, and primer extension. Denaturation is achieved by heating the DNA, while primer annealing and primer extension occur at lower temperatures. The PCR therefore involves temperature cycling, and the DNA polymerase used in the reaction must be tolerant of high temperatures and rapid heating and cooling.

DNA at room temperature in a normal environment is double stranded



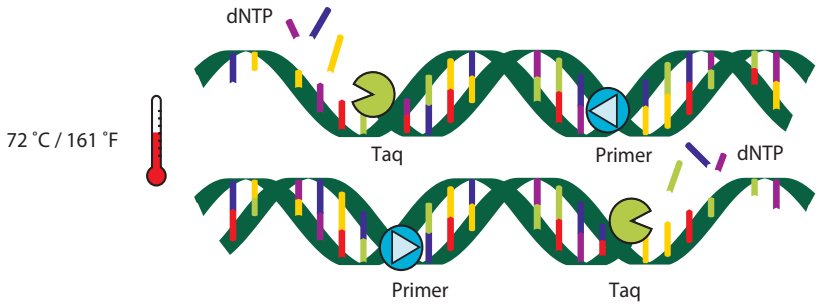
Step 1. Denaturation
The first part of the process separates the two DNA chains. This is done simply by heating the vial to 90–95 ºC (about 201 ºF). The JBAIDS instrument heats up to 92 ºC to separate the double-stranded DNA molecule.

Step 2. Annealing
The primers cannot bind to the DNA strands at such a high temperature, so the vial is cooled to an annealing temperature (45–65 ºC). At this temperature, the primers bind or “anneal” to the DNA strands at a specific sequence.



Step 3. Extension

The final step of the reaction is to make a complete copy of the templates. Since the Taq polymerase works best at around 72 ºC, the temperature of the vial can be raised. Two-step PCR (with longer anneal holds and no extension step) is also possible and may be more advantageous to probe-based real-time chemistries. At temperatures close to the annealing temperatures, Taq enzyme is effective and efficient.



The Taq polymerase begins adding nucleotides to the primer and eventually makes a complementary copy of the template. If the template contains an A nucleotide, the enzyme adds on a T nucleotide to the end of the primer complementary to the target strand. If the template contains a G, it adds a C to the new chain, and so on until it reads the end of the DNA strand. This completes one PCR cycle.

The three steps in PCR—separation of the strands, annealing the primer to the template, and synthesis of new strands—take less than 2 minutes. Each is carried out in the same vial. At the end of a single cycle, each piece of DNA in the vial has been duplicated. A typical PCR program will run a total of 30–50 cycles.

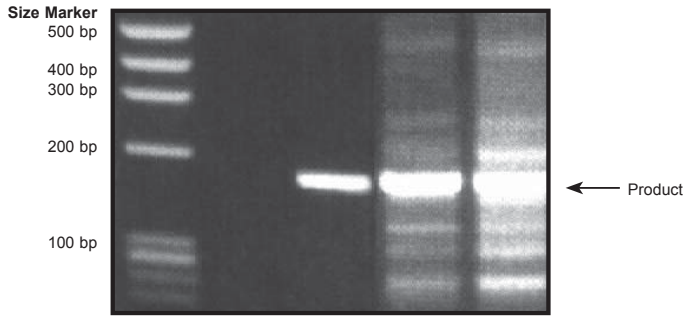
Each newly synthesized DNA piece acts as a new template, so after 30 cycles, 1 billion copies of a single piece of DNA can be produced! Taking into account the time it takes to change the temperature of the reaction vial, 1 billion copies can be ready in less than 30 minutes.

Analysis Methods

Agarose Gel Electrophoresis

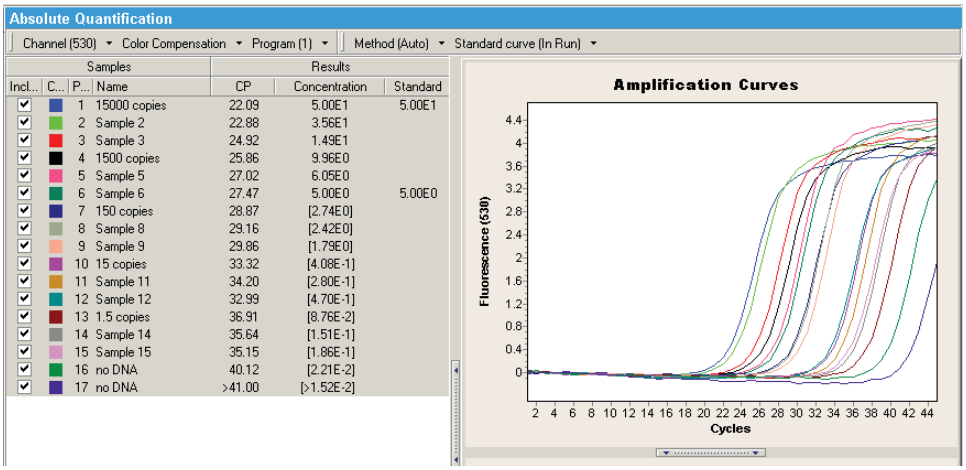
Electrophoresis is a technique used in the laboratory that results in the separation of charged molecules. The DNA molecule is negatively charged and moves by electric current through a matrix of agarose.

Once the PCR cycle is complete, the user needs a tool to view the duplicated product. One conventional method is an agarose gel viewed under an ultraviolet (UV) lamp.



Fluorimetric Detection Real-Time Polymerase Chain Reaction

In real-time PCR, a fluorescent dye or probe is used to measure product.


Absolute Quantification
Channel (530)
Color Compensation
Program (1)
Method (Auto)
Standard curve (In Run)
Samples
Results
Incl... C... P... Name CP Concentration Standard
1 15000 copies 22.09 5.00E1 5.00E1
2 Sample 2 22.88 3.56E1
3 Sample 3 24.92 1.49E1
4 1500 copies 25.86 9.96E0
5 Sample 5 27.02 6.05E0
6 Sample 6 27.47 5.00E0 5.00E0
7 150 copies 28.87 [2.74E0]
8 Sample 8 29.16 [2.42E0]
9 Sample 9 29.86 [1.79E0]
10 15 copies 33.32 [4.08E-1]
11 Sample 11 34.20 [2.80E-1]
12 Sample 12 32.99 [4.70E-1]
13 1.5 copies 36.91 [8.76E-2]
14 Sample 14 35.64 [1.51E-1]
15 Sample 15 35.15 [1.86E-1]
16 no DNA 40.12 [2.21E-2]
17 no DNA >41.00 [>1.52E-2]
Amplification Curves
Fluorescence (530)
Cycles

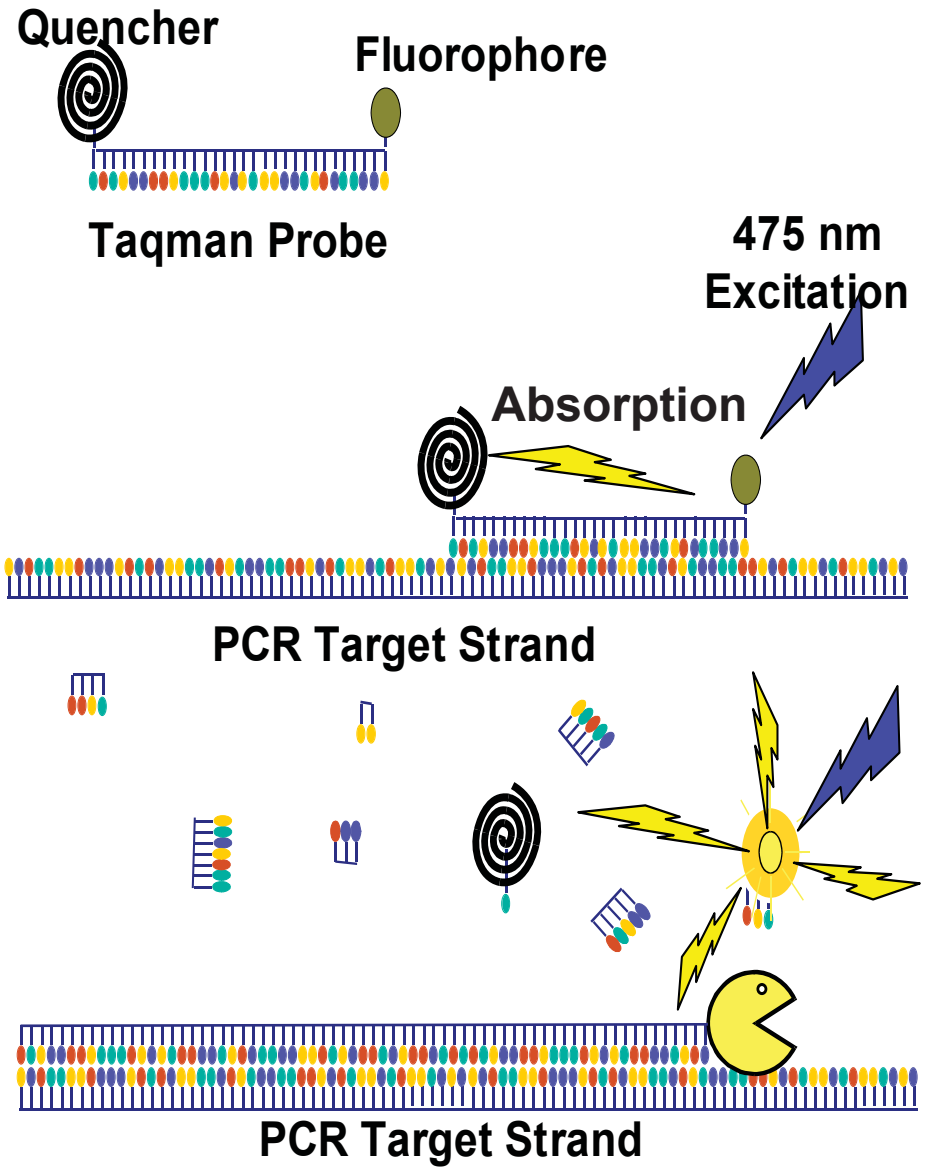
Probes with Fluorescent Dyes Used for Real-Time Polymerase Chain Reaction

Probes are DNA specific and have fluorescent dyes attached to their sequences.

Hydrolysis (TaqMan) Probes

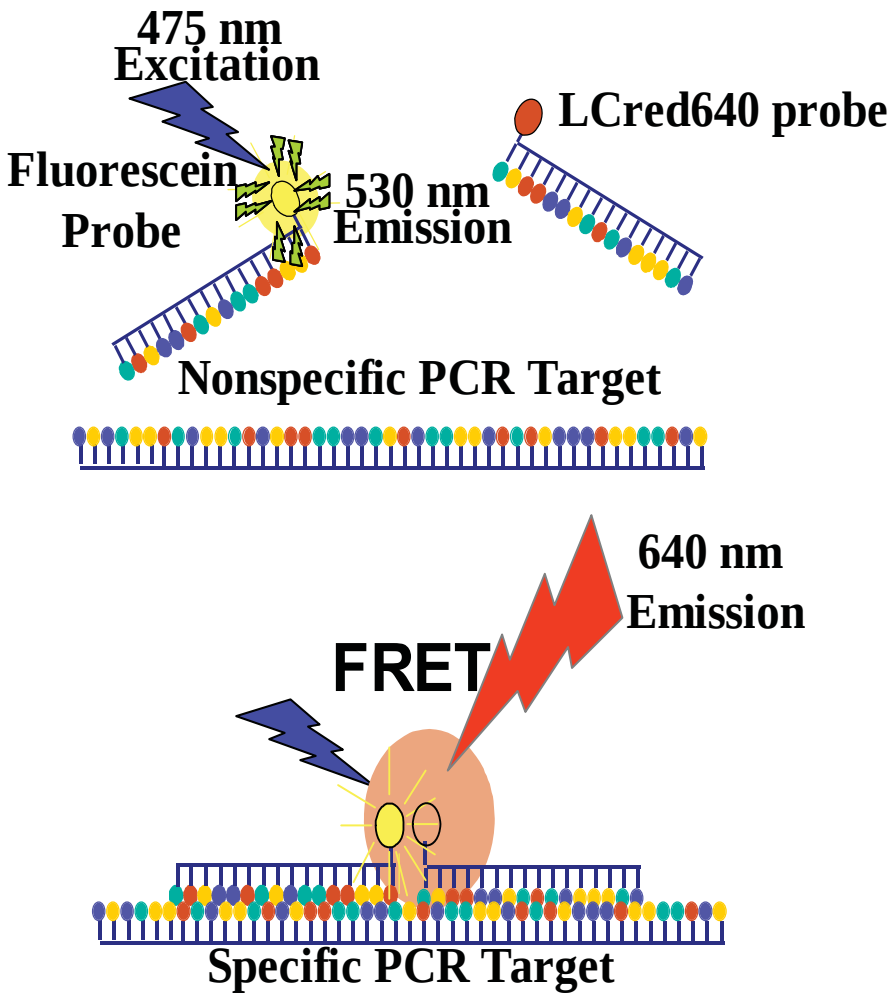
A hydrolysis probe provides a quantitative signal of amplified samples. The shortcoming of this technique is that it doesn't provide a melt profile for subsequent analysis, because the probe is destroyed during the PCR process.

The probe consists of a DNA strand of approximately 20–30 bases with a quencher dye at one end and a reporter (fluorescent) dye at the other end. After the probe hybridizes with the target DNA strand, light from the instrument's LED stimulates the reporter dye to emit a signal, which is absorbed by the quencher. When the Taq enzyme hydrolyzes (decomposes with water) the probe, the quencher is separated from the reporter (along with the synthetic DNA bases), and the excited reporter fluoresces. A detectible signal occurs only when the probe is hydrolyzed by the Taq enzyme. As DNA is amplified, this process repeats, increasing the fluorescent signal of the sample.



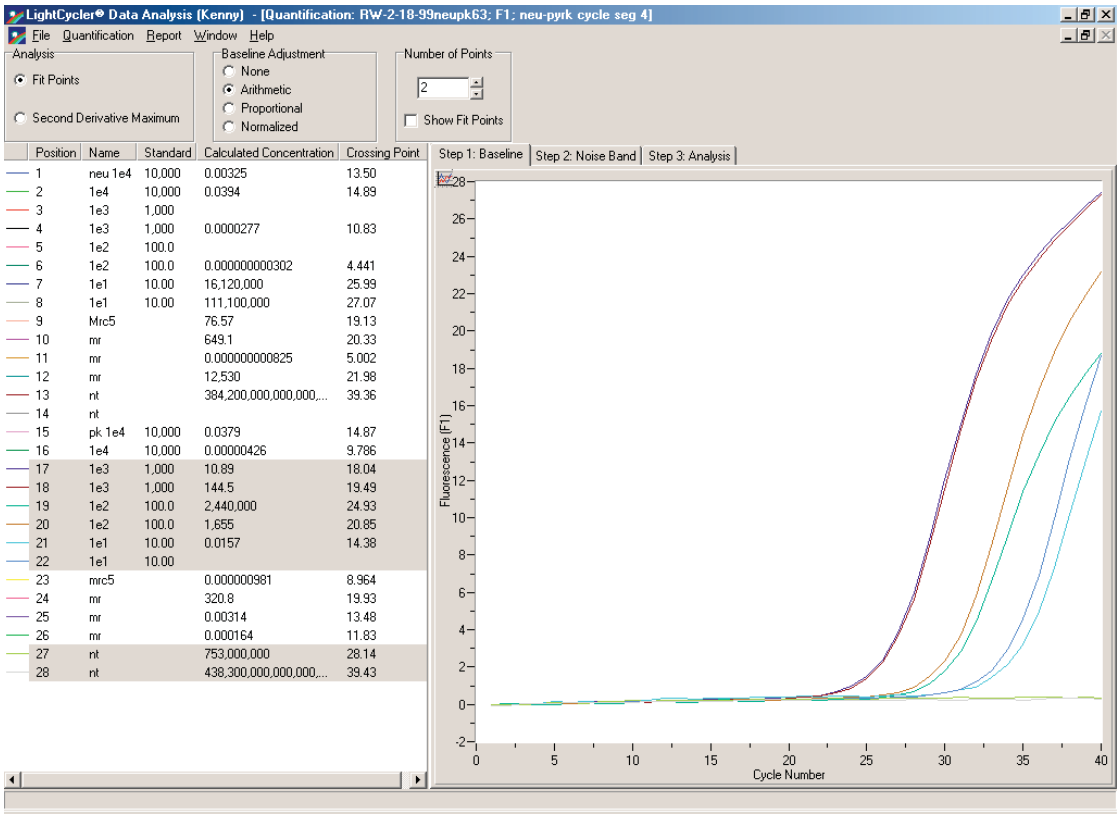
Hybridization Probe

Hybridization probes are composed of a pair of DNA strands designed to hybridize adjacent to each other. Each carries a dye at their facing ends. These fluorophores interact by fluorescence resonance energy transfer (FRET), where the shorter wave dye, fluorescein, excited by blue light from the instrument's optics block, will transfer its energy to the longer wave dye—LCRed 640 in this illustration. This fluorophore emits red light, which is detected in channel 2. Therefore, the signal occurs when both probes bind adjacent to each other. In an excess of probes (typical real-time PCR conditions), the fluorescent signal will be proportional to the accumulated target sequence.



Understanding Sample Crossing Points

In an amplification reaction, the cycle at which the fluorescence of a sample rises above the threshold level of background fluorescence is called the “crossing point” (Cp) of the sample. The presence of a Cp indicates that target DNA is present. A Cp is the point at which amplified product is first visible in the data. The Cp is given to determine the amount of fluorescent PCR product present in a capillary. The software uses the second derivative maximum of each data curve (where the slope of the curve changes) to extrapolate the point where the threshold is crossed. A sample’s Cp is expressed as a cycle number. An earlier Cp indicates the presence of more fluorescent PCR product than a later Cp. The PCR process is exponential; it approximately doubles every cycle. Consequently, a 10-fold dilution should be approximately 3.5 PCR cycles later than an undiluted sample. A sample with a lower initial concentration of target DNA has a higher Cp because it requires more amplification cycles to reach the Cp. A sample with a higher concentration has a lower Cp because it requires fewer cycles.



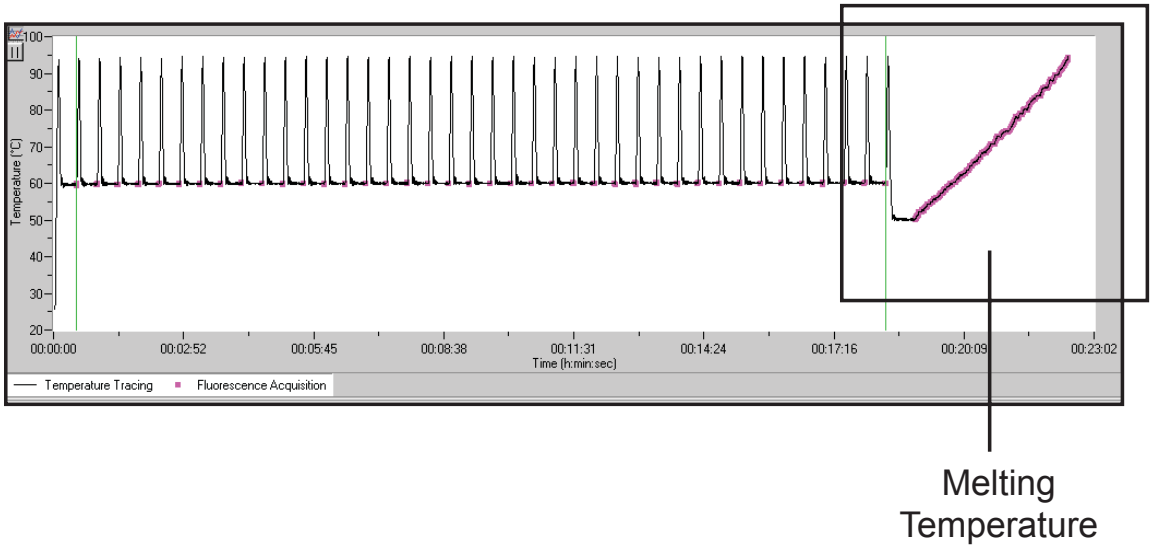
Melting Curve Analysis Using the JBAIDS System

Following a run, the JBAIDS instrument is capable of performing a melting curve analysis on the samples. This analysis is done through temperature denaturation (melting) of the amplified product and the hybridization probe set.

Melting curve analysis can be done with FRET hybridization probe assays (including ITI freeze-dried reagents). Hydrolysis probes (TaqMan) are not capable of exhibiting a melt profile for subsequent analysis.

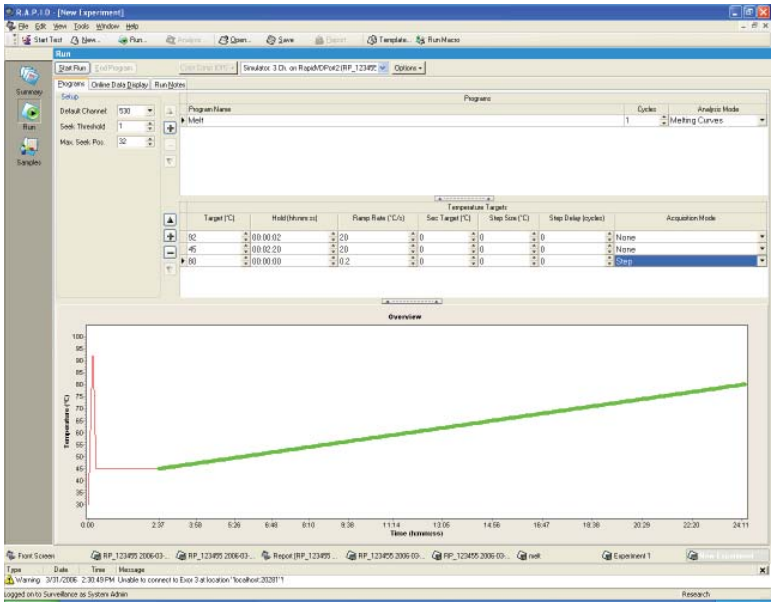
How Melting Curves Work

At the end of a positive reaction, there are millions of copies of target DNA. There are also millions of probe sets still intact within the reaction tube. By lowering the temperature of the reaction, it is possible to hybridize (anneal) a large number of probes to the target DNA producing a high fluorescent signal in the tube. After this hybridization, melting curves are produced by slowly raising the temperature of the reaction tube and monitoring the fluorescence. As the reaction in the tube reaches a particular temperature (probe set and sequence specific) the probes will denature (melt) from the target DNA. This can be observed as a drop in fluorescence at that particular temperature and is referred to as the melting temperature of the probe set or the "Tm."

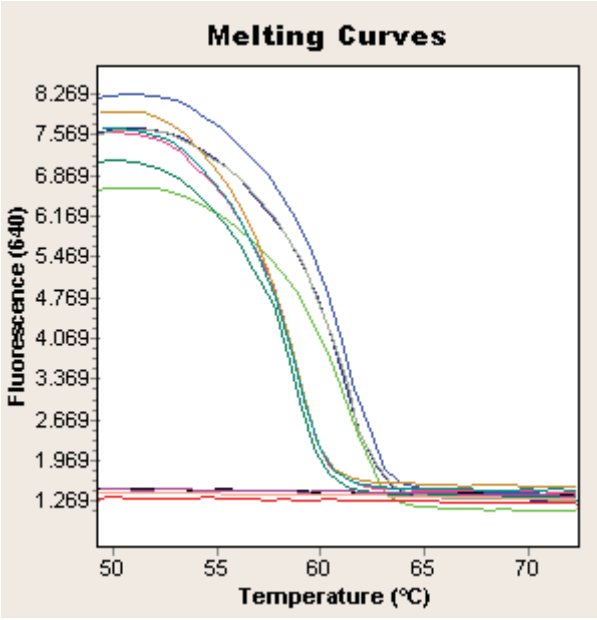


Melting Curve Conditions

Denature temp	92 ºC
Denature time	0 seconds
Acquisition mode	Step or Continuous
Anneal temp	Ramp rate at 0.1–0.2 °C/s
Anneal time	60–180 seconds
Melt begin	At least 10º less than lowest melt peak
Melt end	10º above highest melt peak



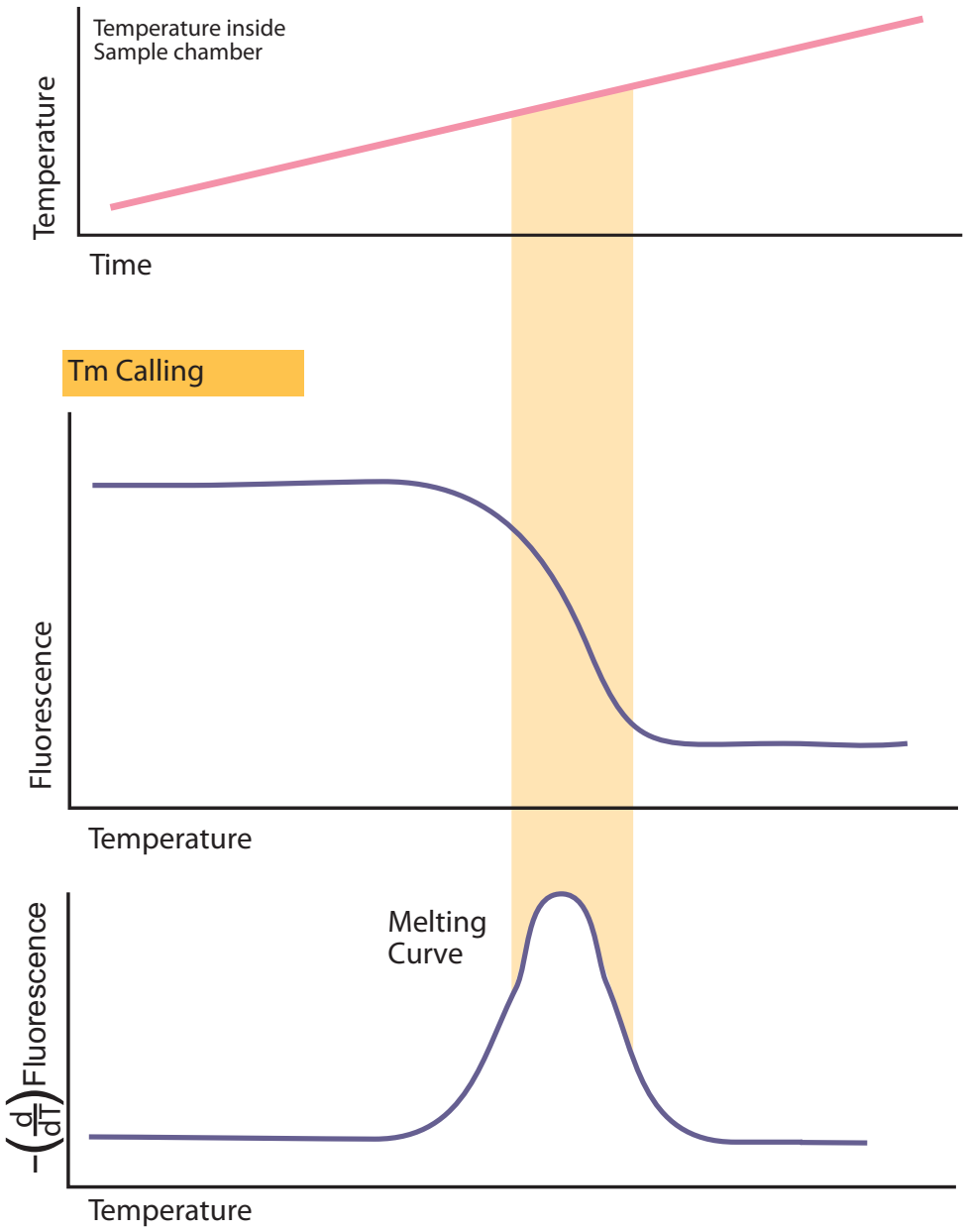
A typical melting temperature profile is illustrated below.



Melting Curve Applications

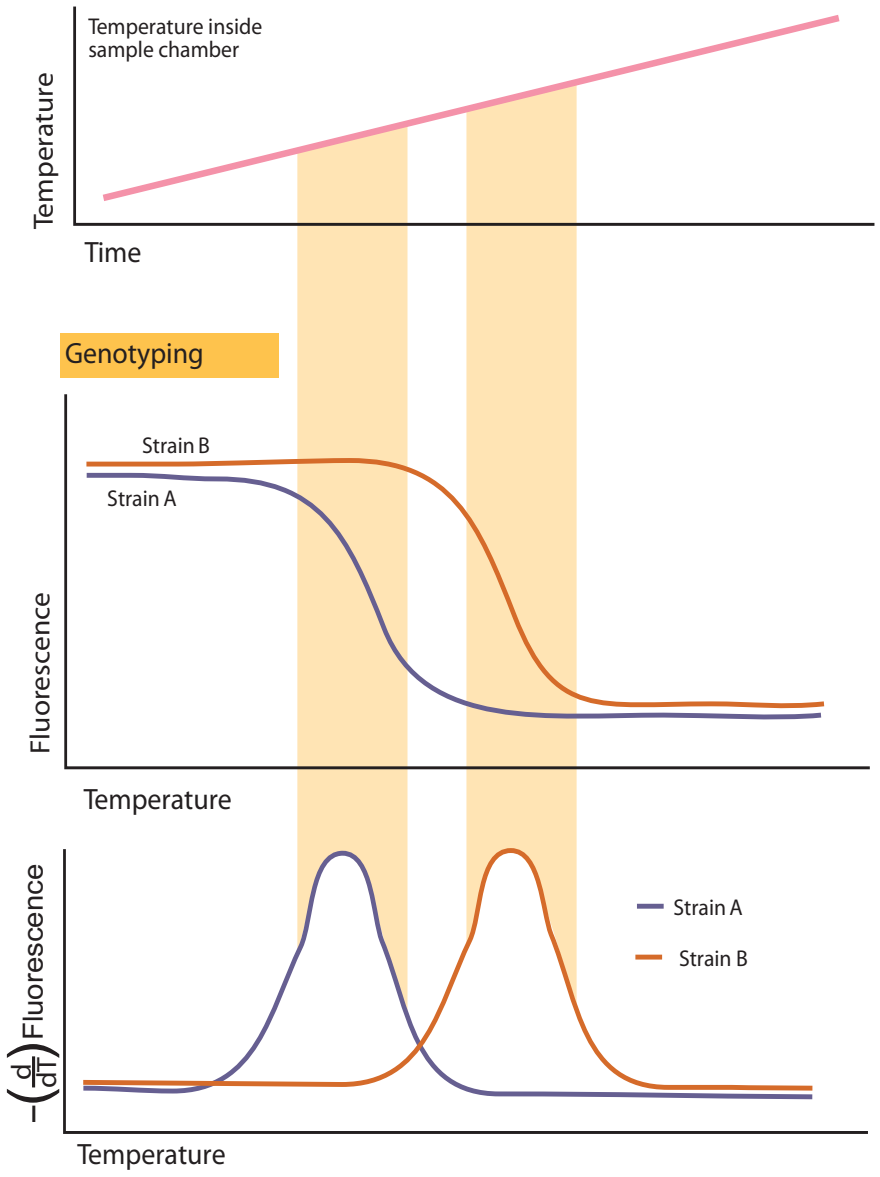
Analysis Confirmation

Melting curve analysis can be used to confirm positively amplified samples. By running a melt profile, a high fluorescence will be observed in positively amplified samples. At the Tm of the probe set, the fluorescence will drop when the probe becomes unbound to the DNA, producing a melting curve (the derivation of this curve is displayed on the bottom graph of the melt analysis and appears as a melting peak).



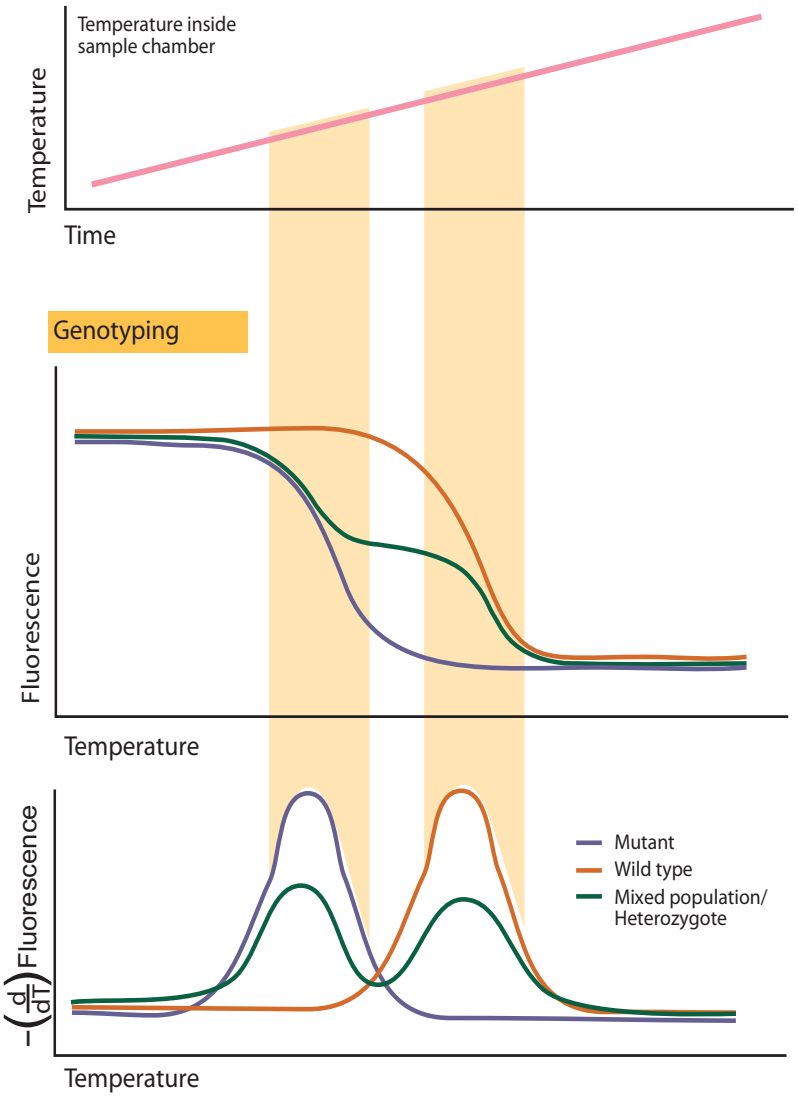
Strain Typing

Using a probe set, it is possible to identify different strains of species. The probe set is designed to perfectly match the genetic sequence of strain A. The difference between **strain A** and **strain B** under that probe can differ by 1 or 2 base pairs. This difference will cause an imperfect annealing (binding event) of the probes and will result in destabilizing the probe. This destabilization can be seen as strain B—the mismatch—melts at a lower temperature than strain A—the perfect match. Strain typing is performed the same way a confirmation melt is performed. The analysis is done by comparing a known species or strain with the unknown sample. Strain A samples will melt at a higher temperature than strain B samples. Samples that have both strain A and B will melt in a stair-step curve and show two derivative peaks.



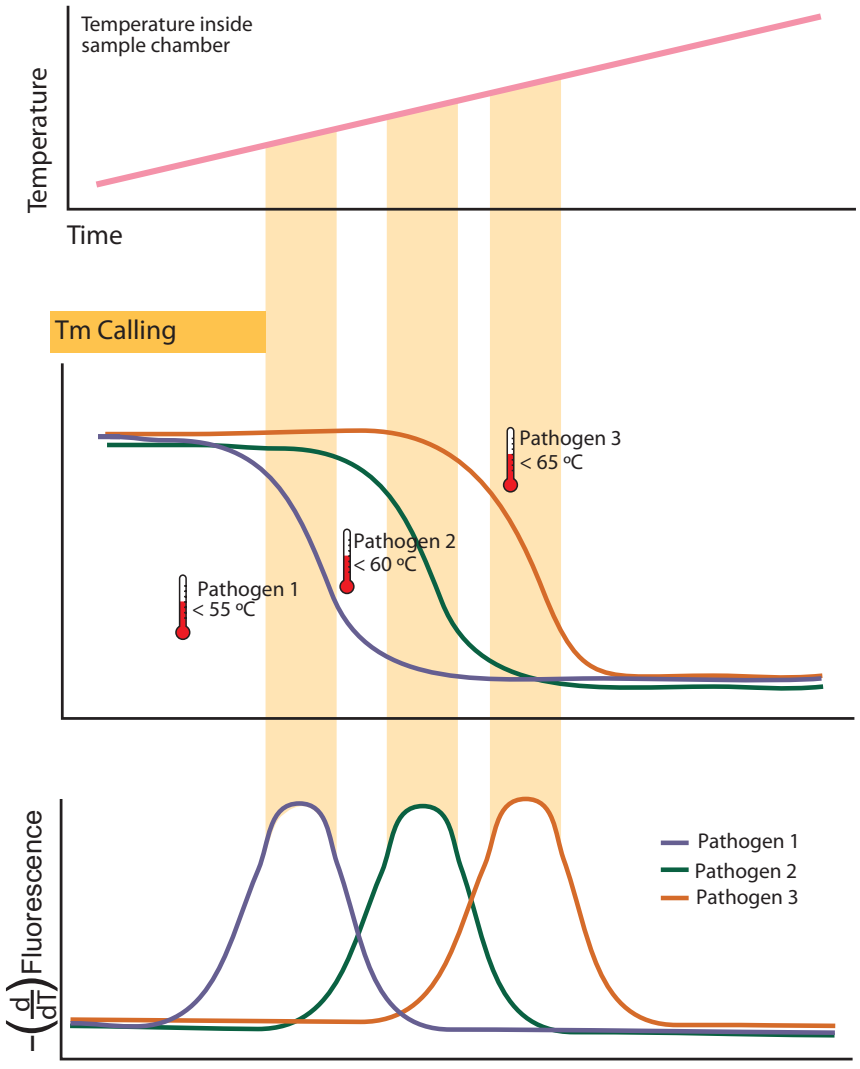
Mutation Detection

Hybridization probe sets can be designed for a specific gene sequence that has a periodic mutation or single nucleotide polymorphism (SNP) and examined and typed by melting curve analysis. The probe set is designed to perfectly match the genetic sequence of a wild type (normal) sample. The difference between the wild type and the mutation under that probe will differ by one base pair. This difference will cause an imperfect annealing (binding event) of the probes and will destabilize the probe. This destabilization can be seen as the mutant—the mismatch—melting at a lower temperature than the wild type. Mutation detection is performed the same way a PCR confirmation melt is performed. Analysis is done by comparing a known wild type with an unknown sample. Wild type samples will melt at a higher temperature than the mutant gene samples. Individuals that have a copy of both the mutant and the wild type will melt in a stair-step like curve and show two derivative peaks.



Tm Multiplexing

It is possible to do detection by melting curve analysis in the same manner as PCR product confirmation. Using this methodology, it is possible to design primer/probe sets of the same color for different organisms that have different melting temperatures (Tm) and mix them in the same tube. **Pathogen 1** p/p set is designed to have a Tm of 55 ºC, **Pathogen 2** p/p has a Tm of 60 ºC, and **Pathogen 3** p/p set has a Tm of 65 ºC. Quantification data during the amplification may be observed (depending on the annealing temperature), but the important confirmatory melting curve analysis must be done. The Tm of each unknown sample that displays a melting curve is examined and matched to the known Tm's of each primer probe set: **Pathogen 1** = 55 ºC, **Pathogen 2** = 60 ºC, **Pathogen 3** = 65 ºC. Samples with multiple organisms can show multiple melting peaks at the designated Tm's. It is also possible to compare these against a known sample (i.e., the positive control) to use as a benchmark for comparison.



Conditions for Successful PCR Performance

Idaho Technology recommends the use of its nucleic acid sample prep kits that are optimized to prepare samples for real-time PCR on the JBAIDS instrument.

For blood samples up to 3 mL, and phosphate-buffered saline (PBS)/water samples up to 5 mL, ITI recommends using the IT 1-2-3™ FLOW DNA Sample Purification Kit.

For powders, nasal swabs, and general environmental samples, use the IT 1-2-3™ SWIPE DNA Purification Kit.

Assay Development

Assay development begins by using Genbank to locate and compare genetic sequences of interest for PCR analysis. GenBank is the National Institute of Health genetic sequence database, an annotated collection of all publicly available DNA sequences. Each GenBank entry includes a concise description of the sequence, the scientific name and taxonomy of the source organism, and a table of features that identifies coding regions and other sites of biological significance, such as transcription units, sites of mutations or modifications, and repeats. Protein translations for coding regions are included in the feature table. Bibliographic references are included along with a link to the Medline unique identifier for all published sequences.

Once the sequence of interest has been determined, primers and probes are designed using software programs. When designing primers, the following guidelines need to be followed:

- Ensure sequence is specific to organism of interest
- Check primer specificity using Basic Local Alignment Search Tool (BLAST) search
- Keep forward and reverse primer Tm's within 1 ºC
- Check primer Tm with Idaho Technology's Tm Utility Software (accessed through www.idahotech.com/downloads_up/index.html#TM_software)
- Limit cross- and self-complementarities

When designing probes, the following guidelines need to be followed:

- Check primer specificity using the BLAST search available at www.ncbi.nih.gov/BLAST
- Ensure that the probe sequence is specific for only one site in the amplicon
- Ensure that probe Tm is approximately 5–10 ºC higher than the Tm of the primers
- If using hybridization probes, ensure that anchor probe Tm is 3–5 ºC above the sensor probe Tm
- Ensure that probes are 23–35 bases in length with a G/C content ranging from 38–60%.
- If possible, avoid high G/C regions, repetitive sequences, single-base repeats, and self- and cross-complementarities between primers and probes

Hybridization Probe Optimization

- Allow one to three bases between anchor and sensor probe
- Label adjacent probe ends, one with fluorescein and the other with LCRed 640 or LCRed 705
- Block 3' ends with fluorescein or phosphate

Assay Parameters and Optimization

If you decide to design your own assays, design the primers and probes first, then test them using the following guidelines:

1. Optimal concentration is the $MgCl_2$ concentration that gives the earliest Cp, the highest end-point fluorescence, and the least nonspecific products, as shown by a gel or melt with double-stranded binding dye.
2. Run an initial run with a 4 mM Mg assay design for primers (concentration used during design) and a 0.2 µM assay design for probes.
    - Set annealing temperature for predicted primer Tm –2 ºC and extension time for number of bp/25 + 3 seconds.
    - Run a gel and confirm product presence and low level of nonspecific products.

If this does not provide necessary sensitivity or detection levels then perform the following protocol:

1. Optimize Mg concentration by doing the following:
    - Run primers with MgCl levels of 2–5 mM
    - Run on gel or melt with double-stranded DNA-binding dye to determine lowest Mg level with fewest nonspecific products and greatest amount of desired product.
2. Optimize Annealing temperature
    - Run primers with different annealing temperatures—start with primer Tm at 0–5 ºC
    - Run on gel or melt with double-stranded DNA binding dye to determine annealing temperature with fewest nonspecific products and greatest amount of desired product.
    - If temperature is too high, primers won't bind target site
    - If temperature is too low, primers will bind to nonspecific sites
3. Optimize extension time using the following formula: length of product/25 + 0–5 seconds
4. Optimize primer titration by testing asymmetric primer dilution series using the following protocol:
    - Select primer concentrations that give best target product and fewest nonspecific products: Unequal primer concentrations are used to drive formation of target strand.
    - Start with combinations of 1-5 µM dilutions
    - If probes bind sense strand, try 5 µM forward primer, 1 µM reverse primer
    - If probes bind anti-sense strand, try 1 µM forward primer, 5 µM reverse primer.
5. Optimize probe titration by testing probes using asymmetric PCR:
    - Use probe concentrations higher than amplicon concentration to promote saturation and greater fluorescent signal
    - Use probe concentrations of 0.2 µM each
6. Add probes with titration of 0.1–1.0 µM

The decision to use asymmetric primers is an easy one to make. This technique is used when it is desirable to amplify more of one strand relative to the other. For example, when using hybridization probes to detect your product, it is often necessary to amplify more copies of the strand *complementary* to the probes. Doing this minimizes binding competition between the probes and the complimentary DNA strand. This facilitates the binding of more probes, increases FRET, and produces a higher signal.

Master Mix Setup

Forward primer	0.1 µM–0.5 µM final concentration
Reverse primer	0.1 µM–0.5 µM final concentration
Sensor probe	0.2 µM final concentration
Anchor probe	0.2 µM final concentration
dNTPs/dUTPs	200 mM each ACGT or 200 mM each ACG and 600 mM U
$MgCl_2$ PCR buffer	2, 3, 4, or 5 mM $MgCl_2$ final concentration
Taq/buffer or KlenTaq /IT enzyme diluent	0.4 units/10 µL reaction or 2.0 units/10 µL reaction

To initially investigate the specificity of the assay, nucleic acid templates from the agent's nearest neighbors should be tested using the PCR conditions previously determined. The nearest neighbors tested should be tested repeatedly with varying concentration to nearest neighbors.

Magnesium Chloride

A $MgCl_2$ titration at 2 mM, 3 mM, 4 mM and 5 mM should be performed to confirm the concentration at which optimal performance is observed. The $MgCl_2$ concentration that gives the earliest Cp, the highest end-point fluorescence (EPF), and the least nonspecific products, as shown by a gel or melt with double-stranded binding dye, will be defined as the optimal concentration. Lower $MgCl_2$ concentrations will limit nonspecific product formation

APPENDIX B:

INSTRUMENT RETURN PROCEDURES

If you are returning an instrument or product for repair, follow the basic guidelines prescribed in this appendix.

The following documents have been provided:

Return Materials Instructions

Declaration of Decontamination

Decontamination Labels

For more information, please visit our Web site at **http://jbaids.idahotech.com** or by phone: (801) 735-6544 or 1-800-735-6544.

RETURN MATERIALS INSTRUCTIONS

Step 1: Obtain a Return Material Authorization Number

The first step in returning an instrument to Idaho Technology is to obtain a return material authorization (RMA) number from our Service Department. Fill out the supplied form and fax or e-mail it to Idaho Technology at (801) 588-0507. This Return Instrument Packet can also be found on the Internet at http://www.idahotech.com/product_sup/forms.htm. Our service representative will contact you with an RMA number and further instructions. If your instrument is still under warranty, please supply the serial number.

Step 2: Decontaminate All Returned Equipment

Equipment returned to Idaho Technology must be handled in a manner that will ensure minimal risk to the personnel involved in packing the instrument for return and to those responsible for receipt, unpacking, and processing at Idaho Technology Inc.

Note: To ensure there is no loss of data, any computers being returned must be backed up before shipping. Idaho Technology is not responsible for any lost data.

The operator must thoroughly decontaminate the instrument by wiping it down with a 10% dilution of household bleach (chlorine bleach diluted 1 part bleach to 9 parts water is approximately 0.5% NaOCl [sodium hypochlorite]), followed by wiping it down with distilled water to remove any bleach contaminants. Be sure not to mix the bleach solution with other chemicals (mixture with acid will liberate chlorine gas). Since the solution is caustic, gloves and a face shield are recommended when preparing and using the solution. When corrosion by the bleach solution may be a problem, flushing with water is permissible after the bleach solution has remained in contact for a minimum of 10 minutes.

Step 3: Decontamination Labels

After the above steps have been completed, the operator must complete and sign two decontamination labels and attach one to the instrument and the other to the exterior of the shipping container. Complete and sign the Declaration of Decontamination form; a photocopy should be made for your records and the original must be returned with the instrument.

Note: An RMA number must be obtained from Idaho Technology before shipping. The RMA number and decontamination labels must be visible on the exterior of the shipping container.

WARNING: Idaho Technology reserves the right to return or refuse receipt of any materials at the customer's expense that do not meet these requirements.

Step 4: Packaging and Shipping

1. Package the JBAIDS instrument inside the instrument backpack in a large heavy-weight box (recommended box size 24" x 18" x 18").
2. Put all extra components in the outside pocket of the backpack and place the instrument topside up into the box. Refer to Appendix E for list of components.

3. Put the accompanying laptop computer in its cardboard box, seal it with packing tape, and place it in the shipping box on top of the instrument. If you do not have the cardboard box, put it inside the padded computer case of the instrument top case.
4. Fill all sides and top of the shipping box around the instrument with at least 2 inches of packaging material for protection against shipping damage.
5. Seal the box with packaging tape.

Idaho Technology reserves the right to return and or refuse receipt of any materials at the customer's expense, that do not meet these requirements.

All returns should be sent to the following address:

Idaho Technology, Inc.
390 Wakara Way
Salt Lake City, UT 84108
USA

DECONTAMINATION FORM

THE FOLLOWING INFORMATION MUST BE COMPLETE TO ENSURE PROPER PROCESSING

1 Equipment Information

Return Materials Authorization number (RMA#): _____

Model Number: _____ Serial Number: _____

Laptop Login and Password (needed to QC test the JBAIDS instrument):

_____

Symptoms: _____

_____

2 Customer Information

Contact Name _____

Company _____

Exact return shipping address _____

_____

_____

3 Decontamination Information

This product must be decontaminated according to Idaho Technology biological decontamination procedures.

What chemical, infectious, toxic or radioactive substances have been in contact with this product? (Also indicate if flammable or corrosive.)_____

4 Authorization Notice

By accepting this authorization to return this product, the user assumes all responsibility for decontamination and cleaning.
Idaho Technology Inc. reserves the right to refuse the delivery of products, which do not appear to have been properly decontaminated.

Date: _____/_____/_____ Signature: _____

Idaho Technology Inc.

Decontamination Form

Decontamination Labels

Please complete these decontamination labels and affix one to the instrument case and the other to the exterior of the shipping carton. Failure to decontaminate before shipping to Idaho Technology Inc. will result in the immediate return of the instrument at your expense.

Copy and cut out the label and attach it to the case of the instrument being returned.

DECONTAMINATION NOTICE:

This Product has been decontaminated per Return Equipment policy: _____

Idaho Technology Return Materials Authorization (RMA#): _____

Customer Name: _____

Customer Address: _____

_____

Signature: _____ Date: ____/___/____

Copy and cut out the label and attach it to shipping container of the instrument being returned.

DECONTAMINATION NOTICE:

This Product has been decontaminated per Return Equipment policy: _____

Idaho Technology Return Materials Authorization (RMA#): _____

Customer Name: _____

Customer Address: _____

_____

Signature: _____ Date: ____/___/____

APPENDIX C:

QUICK GUIDES FOR THE JBAIDS INSTRUMENT

This appendix contains the quick guides for the JBAIDS instrument. These guides have been developed as an abbreviated version of certain tasks that are repeated often and are provided as a guide for a trained operator. For a more detailed description of the items contained in these guides, refer to the detailed sections this manual.

The Following Quick Guides are Provided

- Setting up the JBAIDS instrument
- Setting up the laptop computer

JBAIDS System
Quick Guides

Setting Up the JBAIDS Instrument

1. To unpack the instrument, set the backpack flat on its harness side.
2. Unsnap the four lock-straps and completely unzip the backpack. Open the backpack and remove the instrument case.

3. Set the instrument case on a sturdy flat surface and press the red pressure release button to equalize the pressure inside the instrument case.
4. Open the case by flipping up and turning the case latches counterclockwise and remove the top half of the case. The power and serial cables for the instrument are stored in a pouch in the top of the case and should be removed for use.

5. Rotate the heating duct assembly to the operating position.
6. Follow the instructions for setting up the laptop computer before the instrument is turned on.
7. Plug the instrument power cord into the instrument and the opposite end of the power cord into a surge suppressed grounded power source. Flip the power switch on the top of the instrument to the **ON** position.

JBAIDS System
Quick Guides

Setting Up the Laptop Computer

Use only the supplied serial cables when connecting the instrument to the laptop. Do not use cable extenders to increase the cable length.

1. Remove the laptop computer, power cord, and serial cables from the top of the instrument case.
2. Attach one end of the serial cable to the instrument serial port and the opposite end to the serial port in back of the laptop.

Note: Ensure that the instrument is turned off before plugging in the serial cable.

3. Plug the laptop power cord into the power port in the right side of the laptop and the opposite end of the power cord into a surge-suppressed grounded power source.
4. Open the laptop by pressing down and outward on the lid latch. Lift the screen up and position it for clear and easy viewing.

5. Slide the tab on the front right of the laptop to turn it on. Windows OS will automatically load.
6. Log onto the laptop by entering a user name and password (provided by your lab supervisor or systems administrator). The instrument software uses the Common Operating Environment (COE) as outlined by the DOD to manage user information and access privileges.

APPENDIX D:

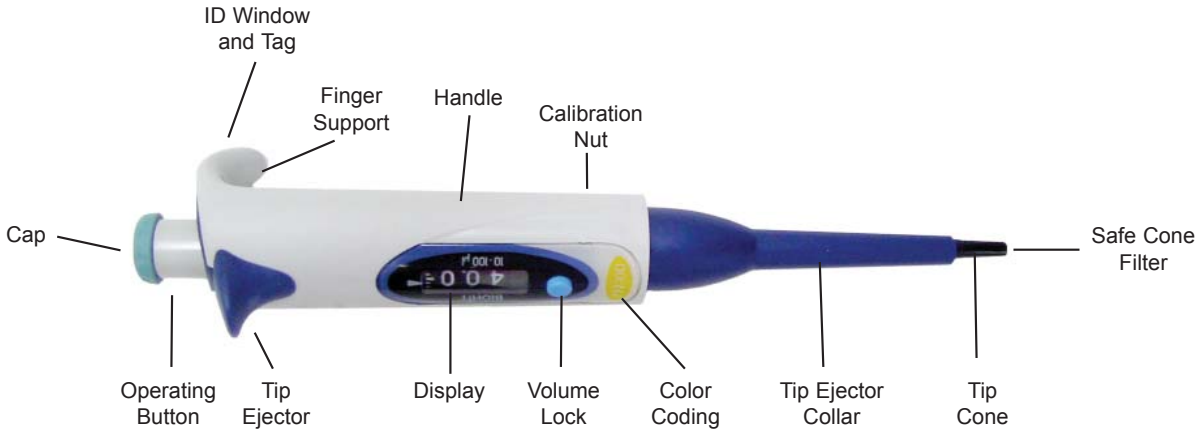
PIPETTING BASICS

This appendix provides basic information on the techniques of operating a pipette. For more detailed information, refer to the JBAIDS Operator Training Manual as well as the instruction manual that came with the pipette.

Setting the Volume

The volume of liquid to be aspirated is set using the volumeter. The volumeter consists of three number-dials, which are read from left (most significant digit) to right (least significant digit). A marker is used to set exact or intermediate volumes using the scale on the right side of dial. The dials are colored in black.

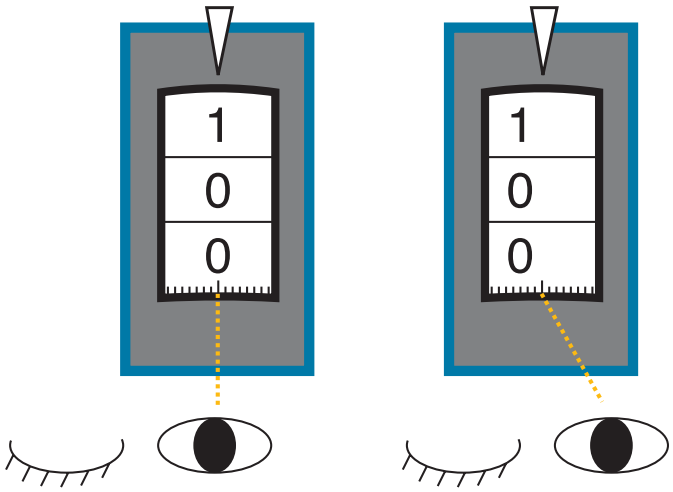
1. The volume is set by pressing the volume lock and holding it down.
2. Next set the volume by rotating the operating button (clockwise to decrease the volume and counterclockwise to increase).
3. Finally release the volume lock. Do not rotate the operating button without pressing down the volume lock. Do not rotate the operating button outside the volume range of the pipettor.



To obtain maximum accuracy when setting the volume, proceed as follows:

- When decreasing the volume setting, slowly reach the required setting, making sure not to overshoot the mark.
- When increasing the volume setting, pass the required value by one-third of a turn and then slowly decrease the volume to reach the volume, making sure not to overshoot the mark.

To avoid parallax errors, make sure that the volume indicator and the selected volume marking are in your direct line of vision. At close range you may find it helps to close one eye.



Sealing and Ejecting Tips

Before fitting a tip, ensure that the pipettor tip cone is clean. Press the tip on the tip cone of the pipettor. The pipettor is provided with a spring loaded tip cone for optimal sealing.

Eject the tip by pressing the tip ejector with your thumb. Make sure that the tip is disposed into a suitable waste container.

Note: If the tip is pressed too hard, the tip cone yields and, as a result, the counter and operating button moves.

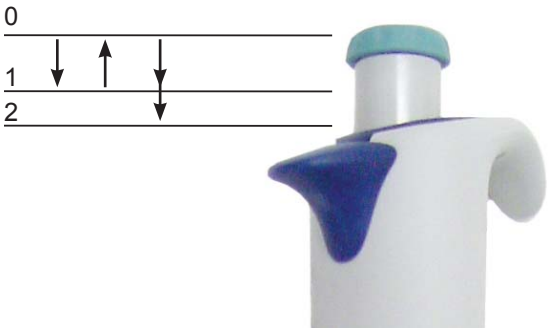
Pipetting Techniques

Two basic pipetting techniques, forward and reverse pipetting, are associated with pipettors. Forward pipetting is the most commonly used pipetting method. The technique employs the blowout function ensuring complete delivery of the liquid. Reverse pipetting is recommended for highly viscous, biological, or foaming liquids, or very small volumes of liquid. A selected volume plus an excess is aspirated into the tip. The delivery is done without blowout, and, thus, the excess volume remains in the tip. The reverse technique also facilitates the repeated delivery of the same volume.

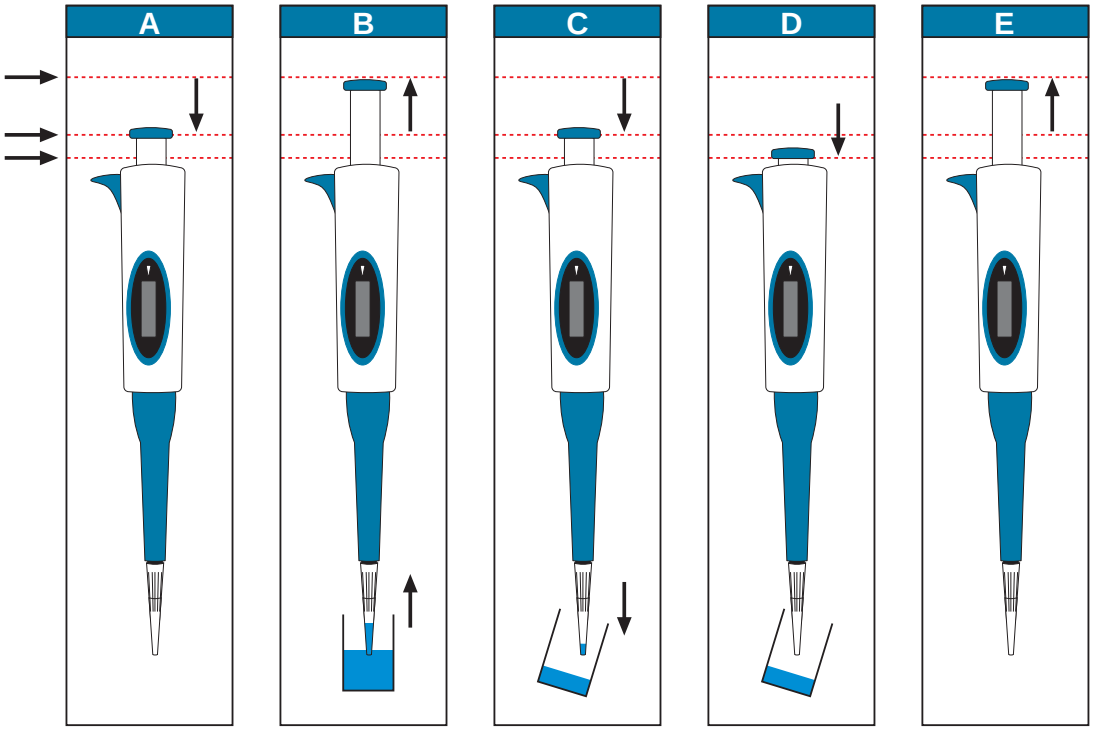
Forward Pipetting

1. Fit the tip onto the pipettor tip cone.
2. Press the operating button to the first stop.
3. Place the tip just under the surface of the liquid (2–3 mm) and smoothly release the operating button up to the starting position. Wait 1 s. Carefully withdraw the tip from the liquid, touching against the edge of the container to remove excess from the outside of the tip.

4. Dispense the liquid by pressing the operating button to the first stop. After a short delay, press the operating button to the second stop. This action will empty the tip.



Forward Pipetting

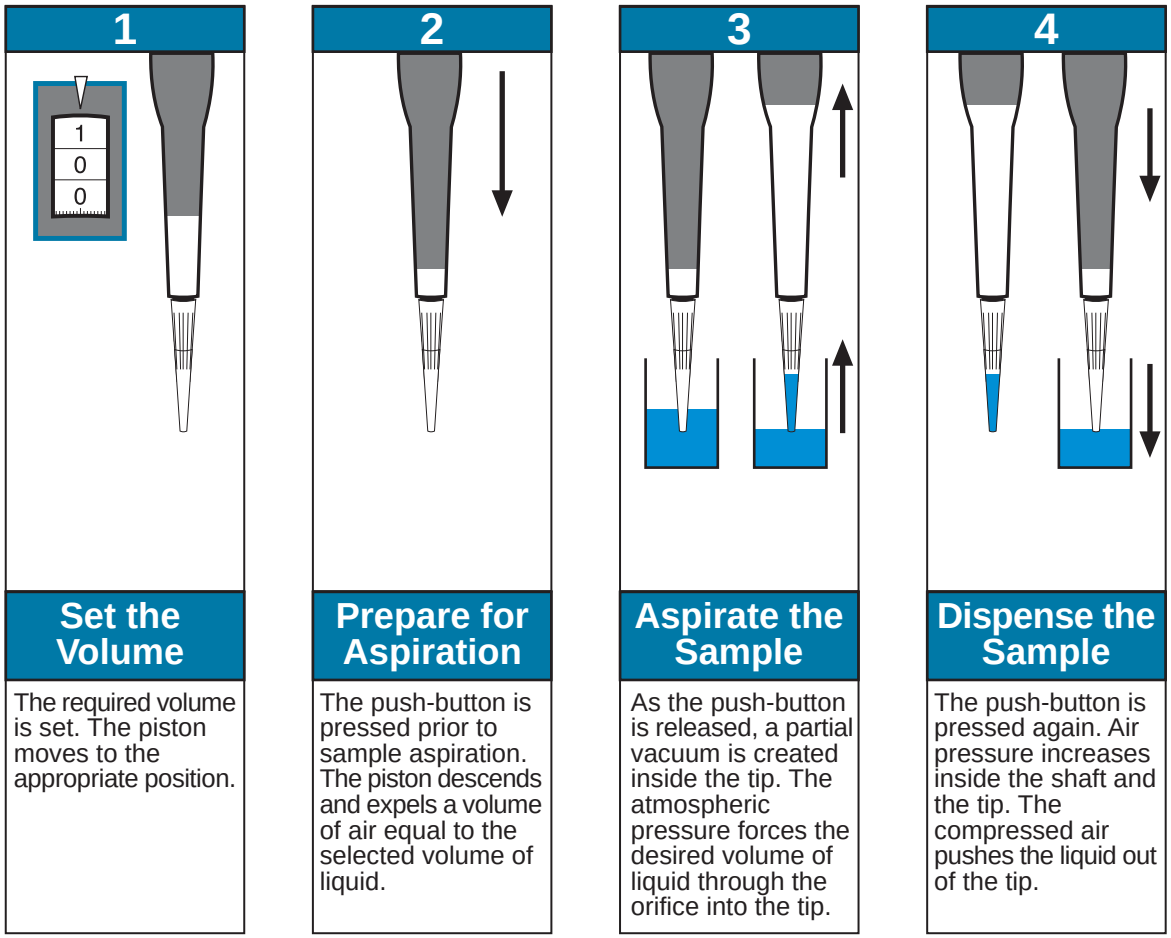


Reverse Pipetting

1. Fit the tip onto the pipettor tip cone.
2. Press the operating button all the way to the second stop.
3. Place the tip just under the surface of the liquid (2–3 mm) and smoothly release the operating button up to the starting position.
4. Withdraw the tip from the liquid touching against the edge of the container to remove excess.
5. Press the operating button smoothly to the first stop to deliver the present volume. Hold the operating button at the first stop. The liquid that remains in the tip should not be included in the delivery.
6. Discard the remaining liquid with the pipette tip.

How Do Air-displacement Pipettes Work?

When the push-button is pressed on an air-displacement pipette, the piston inside the instrument moves down to let air out. Air is displaced by the piston. The volume of air displaced is equivalent to the volume of liquid aspirated. The schematic drawings (below) show how the piston determines the volume of air displaced and, subsequently, the volume of sample aspirated.


1
1
0
0
Set the Volume
The required volume is set. The piston moves to the appropriate position.
2
Prepare for Aspiration
The push-button is pressed prior to sample aspiration. The piston descends and expels a volume of air equal to the selected volume of liquid.
3
Aspirate the Sample
As the push-button is released, a partial vacuum is created inside the tip. The atmospheric pressure forces the desired volume of liquid through the orifice into the tip.
4
Dispense the Sample
The push-button is pressed again. Air pressure increases inside the shaft and the tip. The compressed air pushes the liquid out of the tip.

Pipetting Steps

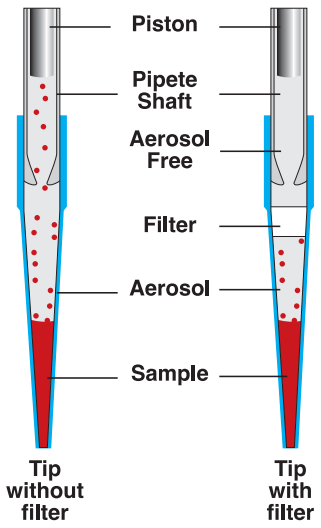
1. First organize your workstation for maximum efficiency and minimum fatigue.
   - Adjust your chair or stool so that the work surface is at the right height when you are sitting straight
   - If possible, always try to work with your hands below shoulder height
   - Reduce the height of applications such as gel loading, if possible
   - Use adjustable tables and workbenches if possible.
2. Make sure the tip is properly mounted and fits well before you set the volume.
3. Hold pipette vertically.
4. Adjust the volume.
5. Choose the mode of pipetting (reverse or forward mode) adapted to your sample.

6. Pay special attention to smooth pipetting:
   - To favor uniform timing and motion, have all necessary objects within easy arm's reach.
   - Place the most frequently used objects in front of you. The more rarely used items can be placed a little further away from you.
   - Place the opening of the receptacle for used tips at the same height as the end of your pipette.
   - Always use aerosol-barrier pipette tips.
   - Avoid rough handling and avoid dropping the pipettor.
7. Place the tip only a few millimeters into the liquid. Draw and expel the water slowly.
8. Eject the used tip and store the pipette in an upright position to avoid damage and cross-contamination.
9. Don't drop the pipette. It is wise to clean and test the performance of the pipette regularly.
10. Take time to relax
    - If possible, try to switch periodically between different types of work.
    - Keep an appropriate, unrushed working speed. Let go of the pipette from time to time and give the fingers/hand a (micro) break.
    - Take frequent short breaks. Change your sitting position. Lean back and relax your shoulders and arms.

For Adjustment and Calibration, please go to http://www.biohit.com

Types of Tips Used with BioHit mLine

Tips are made of premium-grade virgin polypropylene and incorporate a hydrophobic barrier to prevent contamination of the pipettor barrel and subsequent sample cross-contamination. They are graduated for quick reference to volumes being pipetted and are certified RNase-, DNase-, and pyrogen-free.



APPENDIX E:

JBAIDS INSTRUMENT PARTS LIST

The following tables provide lists of items that are included with the JBAIDS instrument as well as items that are required and recommended to perform pathogen analysis. Descriptions, part numbers, and national stock numbers (NSN) for these items have been included to make ordering easier. All JBAIDS instruments, computer, and accessories (freeze-dried reagents, purification kits and supplies**)** can be ordered from Idaho Technology Inc. Please contact Idaho Technology to report defects in materials or manufacture. This will help us improve the quality or model of product offered.

Item	Part Number	NSN Number
JBAIDS Instrument	JRPD-ASY-0001	6665-01-523-5629
Laptop Computer	COMP-SUB-0002	6665-01-524-2745
Drive, DVD/CDRW for Panasonic Toughbook 29	COMP-GEN-0004	
220V Conv. Kit	ELEC-CAB-0016	
USB Flash Drive	SDCZ2-256-A10	6515-01-531-3559
Backpack	RAPD-CAS-0008	6665-01-523-4902
Case Pouch Start-Up Kit	JRPD-CAS-0002	6665-01-523-7278
Case Pouch Laptop	RAPD-CAS-0003	
Zipper Pouch Mini-Centrifuge	JRPD-CAS-0004	6665-01-523-7290
Zipper Pouch Sample Reaction Capillaries	JRPD-CAS-0005	6665-01-523-7289
Zipper Pouch Serial & Power Cables	JRPD-CAS-0006	6665-01-523-7293
Mini-centrifuge 120V	ITI-5215	6640-01-518-4675
Serial Cable, (DB9)	ELEC-CAB-0001	6665-01-524-2561
Cord, Power 100V-120V	POWR-CRD-0001	6665-01-524-2698
Cord, Power 220V-230V	POWR-CRD-0002	6665-01-524-2564
JBAIDS Manual	JRPD-PRT-0001	7610-01-523-9200
Quick Guides	JRPD-PRT-0004	
JBAIDS Installation CD	JRPD-SCD-0001	
Tool Kit	JRPD-ASY-0003	6665-01-524-2743
20 Pocket Tool Pouch	JRPD-CAS-0003	6665-01-524-2699
Driver, Hex, 5/64"	ITI-5227	5120-01-500-6251
Screwdriver, Phillips, #0	TOOL-DRV-0005	6665-01-524-2797
Driver, Hex, 1/8"	TOOL-DRV-0006	6665-01-524-2702

Item	Part Number	NSN Number
Loctite 222 Threadlocker Adhesive	CHEM-GEN-0033	6665-01-524-2547
Driver, Ball 5/32" Hex, 3 39/64" Blade Length	TOOL-DRV-0008	6665-01-524-2502
Driver, T-Handle 3/32" Hex, 9" Blade Length	TOOL-DRV-0009	6665-01-524-2507
Driver, Standard Screwdriver 1/8" Tip Width	TOOL-DRV-0010	6665-01-524-2513
Driver, Standard Nut Driver 3/16", 3" Shaft	TOOL-DRV-0011	6665-01-524-2517
Driver, Standard Nut Driver 1/4", 3" Shaft	TOOL-DRV-0012	6665-01-524-2522
Lubricant, Tri-Flow PTFE	CHEM-GEN-0034	6665-01-524-2550
Brush, Nylon	TOOL-GEN-0001	6665-01-523-7267
Start-up Kit	JRPD-ASY-0005	6665-01-523-4904
Centrifuge Adapters 1.5mm (6)	ITI-1750-1.5	
Lens Cleaning Tissue	ITI-1802	
Lens Cleaning Solution	ITI-1803	
Sample Reaction Capillaries	ITI-1909339	6630-01-523-4982
Repair Parts Kit	JRPD-ASY-0009	
Chamber Fan Motor Assembly	JRPD-SUB-0021	6550-01-529-2860
Serial Cable Receptacle	ELEC-CAB-0022	6650-01-525-7518
Case Blower Filter and Retainer	FANS-CVR-0003	6550-01-529-2855
Case Blower Assembly	JRPD-SUB-0016	6550-01-529-2841
Chamber Fan Blade Assembly	JRPD-SUB-0020	6550-01-529-2846
Lithium Battery	BATT-GEN-0003	6665-01-525-7531
Fuse, Power Switch	FUSE-GEN-0002	6665-01-525-7538
Power Switch	POWR-ENT-0001	6665-01-5225-7539
Screw, 6-32x1/4 button, Pack of 5 (chamber fan, platter)	S0632BHT-0.250	
Jack Screw, Pack of 5 (serial receptacle)	HARD-GEN-0053	
Hex Standoff, 6-32x1", pack of 5 (power switch mod.)	T0632FHQB1.000	
Screw, 10-32x3/8" button,pack of 5 (deck plate)	S1032BHK-0.375	
Washer, #6 split lock, pack of 5 (chamber fan)	W06ST-0000	
Screw, 6-32x7/16" flat, pack of 5 (case blower)	S0632FHT-0.438	
Screw, 6-32x1.25" flat, pack of 5 (belt cover)	S0632FHK-1.250	
Sample Purification Kits and Supplies		
IT 1-2-3™ SWIPE Sample Purification Kit	ASAY-ASY-0005	6550-01-529-4828
IT 1-2-3™ FLOW Sample Purification Kit	ASAY-ASY-0004	6550-01-529-4820
IT 1-2-3™ SCOOP Sample Purification Kit	ASAY-ASY-0502	6550-01-529-4812
ITI 1-2-3™ VIBE Sample Purification Kit	ASAY-ASY-0500	6550-01-529-4833
ITI 1-2-3™ RNA Module	ASAY-ASY-0501	6550-01-529-4839

Item	Part Number	NSN Number
Filtered Stomacher Bags	ASAY-ASY-0060	6640-01-528-3012
PBS packets	ASAY-ASY-0061	6550-01-528-9630
Triton X-100	ASAY-ASY-0062	6550-01-528-9651
Stool Collection Vials (Cary Blair)	ASAY-ASY-0063	6530-01-529-0108
Stool Concentrator Filters	ASAY-ASY-0064	6530-01-529-0121
Freeze-Dried Reagents		
Assay-Yersinia Pestis Target 1-Plague	JRPD-ASY-0102	6550-01-523-5642
Assay-Yersinia Pestis Target 2-Plague	JRPD-ASY-0101	6550-01-523-5936
Assay-Orthopox	JRPD-ASY-0100	6550-01-523-5947
Assay-Variola (Smallpox)	JRPD-ASY-0115	6550-01-523-5939
Assay-Bacillus Anthracis Target 1-Anthrax	JRPD-ASY-0103	6550-01-523-5948
Assay-Bacillus Anthracis Target 2-Anthrax	JRPD-ASY-0104	6550-01-523-5949
Assay-Francisella Tularensis (Tularemia)	JRPD-ASY-0105	6550-01-523-6620
Assay- Brucella Melitensis (Brucellosis)	JRPD-ASY-0106	6550-01-523-6621
Assay-Coxiella Burnetii (Q Fever)	JRPD-ASY-0122	6550-01-523-6624
Assay-Rickettsia Prowazekii (Typhus)	JRPD-ASY-0108	6550-01-523-6623
Assay-Burkholderia Spp. (Glanders)	JRPD-ASY-0109	6550-01-523-6622
Assay-Ebola Virus (Hemorrhagic Fever)	JRPD-ASY-0110	6550-01-523-6625
Assay-Marburg Virus (Hemorrhagic Fever)	JRPD-ASY-0111	6550-01-523-5956
Assay-Eastern Equine Encephalitis Virus	JRPD-ASY-0112	6550-01-523-5957
Assay-Western Equine Encephalitis Virus	JRPD-ASY-0113	6550-01-523-4920
Assay-Venezuelan Equine Encephalitis Virus	JRPD-ASY-0114	6550-01-523-4900

Note: All common laboratory equipment and supplies shall be ordered via the Department of Defense supply system channels.

Item	NSN Number
Common Laboratory Supplies and Consumables	
Adapter, 10 Ml Set Of 2 p/n 368331	6640-01-529-4254
Adapter, 4.5 Ml, Set Of 2 p/n 392259	6640-01-529-4250
Adapter, 50 Ml Set Of 2 p/n 392254	6640-01-529-4252
Adapter, for Heatblock, 1.5 mLTubes	6640-01-531-2960
Adapter, for Heatblock, 15 mLTubes	6640-01-537-9989
Adapter, for Heatblock, 50 mL Tubes	6640-01-531-2955
Adapter, Only Iti 15 Ml F/ Beadbeater	6640-01-529-6714
Bag, Med, Autoclave, Red 2 Mil	6530-01-529-4540
Bag, Sm, 8 x 12, Autoclave	6530-01-529-4536
Bag, Ziplock, Biohazard, 6 x 9"	6530-01-349-2767
Beadbeater, Only 2 mL Disruptor Genie	6640-01-531-3058

Item	NSN Number
Bleach, Household Clorox ~5%, 24oz	6810-01-517-5370
Bottle, 500 mL Wash Bottle	6640-01-336-0614
Cable, Printer, USB A/B	6515-01-531-3527
Cable, USB Extension, Type A/A	6515-01-531-3533
Capillaries, for JBAIDS Samples, 768 tubes/box	6630-01-523-4982
Cartridge, Printer Ink, Black	7510-01-532-1960
Cartridge, Printer Ink, Color	7510-01-532-2166
Case, for Biosafety Hood	NSN UNK
Case, for JBAIDS Misc [Minispin]	NSN UNK
Case, for Tabletop Centrifuge	NSN UNK
Centrifuge, Allegra X-22, 115 Volt	6640-01-528-6196
Chair, Adjustable Height	6530-01-518-5799
Container, 1 Liter, 6 Bottles/Pk	6640-01-537-9986
Container, Infectious Shipping, 12/cs	6640-01-532-5554
Container, Liquid Med Waste (40/cs)	6530-01-390-2433
Container, Sharps, 1 gallon	6530-01-481-8689
Cover, Bucket, Set Of 4 p/n 392264	6640-01-528-6238
Dispenser, for 1/2" X 500" Tape	7520-01-531-2968
DNA Away, Surface Decontaminant	6640-01-509-0794
Extension Cord, Heavy Duty	6150-01-531-5025
Eye Wash Solution, Sterile, 1 Liter	6640-01-530-3012
Eye Wash Station	4240-01-310-0636
Forceps, Thumb Dressing	6515-01-530-3011
Glove, Patient Exam XL	6515-01-519-9174
Glove, Patient Exam, Large	6515-01-519-9161
Glove, Patient Exam, Medium	6515-01-519-9172
Glove, Patient Exam, Small	6515-01-519-9173
Heatblock, Dry, Digital, 4-block 115V	6640-01-531-2990
Holder, For Small Biohazard Bag	6530-01-460-8451
Hood, Biosafety Class I	6640-01-528-6988
Knife, Steel Utility (Each)	5110-01-538-3943
Labcoat, Lg, Cuff, Fluid Resist, 25/cs	6532-01-363-0541
Labcoat, Md, Cuff, Fluid Resist, 25/cs	6532-01-363-4480
Labcoat, Xl, Cuff, Fluid Resist, 25/cs	6532-01-363-0542
Marker, Fine, Lab (Box of 10)	7520-01-249-6421
Mask, Reg, PFR95, 0.3 mic, 35/pk, (1/2 Cs)	6532-01-450-2057
Mask, Sm, PFR95, 0.3 mic, 35/pk, (1/2 Cs)	6532-01-459-0428
Memory, USB Flash Drive, 256 Mb	6515-01-531-3559
Minispin Space Centrifuge, 120V	6640-01-528-5623
Mixer, Vortex Genie 2, 120V	6640-00-926-1290
Paper, for Bench, Underpad	6640-01-268-5486

Item	NSN Number
Paper, Printer, 8.5" X 11"	7530-01-200-2203
Parafilm, 4" X 250'	6640-01-146-4248
Pen, Medium Ball Point	7520-01-279-9645
Pencil, Wax (box of 12)	7520-00-223-6672
Pipettor, Mline Mechanical, 100 µL	6640-01-528-8422
Pipettor, Mline Mechanical, 1000 µL	6640-01-528-8439
Power Outlet Strip	6150-01-531-5034
Printer, Portable, Deskjet Hp5740	7025-01-530-0983
Rack, Tube, Flips 4-way, 5/pk	6640-01-531-2984
Refrigerator / Freezer Combo, 115V	NSN UNK
Rotor Assembly, Model Sx-4250	6640-01-528-6256
Scale, Top Load Balance, 115V	6670-01-528-5185
Screwdriver, Interchangable Bits	5120-01-538-6299
Shield, Splash, Disposable	6515-01-374-6757
Spatula, Sterile, Disposable, 100/cs	6640-01-529-0780
Spill Kit, Biological Hazard (1/6 cs)	4240-01-310-0637
Stand, For 3-foot Class I Hood	6640-01-529-0766
Stand, Pipettor, Rotary, Carousel	6640-01-528-8715
Table, Hinged Top, Center Folding	ASIO-MIS-0017
Tape, Lab, White, Labeling, 1/2" X 500"	7510-01-529-4264
Thermometer, Long Stem	6640-01-529-3085
Thermometer, Refrigerator	6685-01-531-2981
Timer, Led Display	6645-01-459-1499
Tip, Pipettor, Art, 100 µL, 960 Tip/pk	6640-01-528-8607
Tip, Pipettor, Art, 1000 µL, 576 Tip/pk	6640-01-528-8586
Tool, Capillary Capping	6640-01-532-7235
Towel, Paper. Wypall, 1260/cs	8540-01-529-6543
Tube, Conical, 50mL, 50 tubes/bag	NSN UNK
UPS, Uninterruptible Power Supply	6130-01-497-1363
Weighboat, Medium, 500/cs	6670-01-014-7211
Work Surface, Epoxy, for Hood	6640-01-528-6984

GLOSSARY OF TERMS

Annealing: The second step in a PCR cycle where the primers bind the DNA sequence to initiate product extension. This step is optimized according to the melting temperature of the primers (i.e., 40–65 ºC).

Batch Test: A mode in the JBAIDS software that allows the user to assay a single organism from multiple samples.

CCC: Choose Color Compensation. In multiplex (dual-color) PCR reactions, a file used to compensate for bleed-over of fluorescence signal between channels.

Conjugated (i.e., attached): Containing two or more double or triple bonds in alternation with single bonds. Used to describe a double chemical bond separated by a single bond.

DNA: Deoxyribonucleic acid. One of two types of molecules that encode genetic information. (The other is RNA. In humans DNA is the genetic material, and RNA is transcribed from it. In some other organisms, the reverse occurs: RNA is the genetic material, and DNA is transcribed from it.)

Denaturation: The first step in a PCR cycle where the double-stranded DNA is melted at high temperature (92 ºC) into single strands.

Excitation: The light energy transfer between the dyes on two hybridization probes in close proximity when bound to a DNA strand.

FAM: 6-carboxyfluorescein. A fluorescence dye commonly used in hydrolysis probes, detected in channel 1 on the JBAIDS instrument.

Fluorescence Monitoring: Measurement of light emitted from a fluorescent probe.

Fluorescein (FITC): 5-carboxyfluorescein. Commonly used in hybridization probes.

F.R.E.T.: Fluorescence Resonance Energy Transfer. Light energy transfer between the dyes on two hybridization probes in close proximity when bound to a DNA strand.

Gel Electrophoresis: Separation of nucleic acid or protein through a matrix of either agarose or polyacrylamide by subjecting it to an electric field.

Hydrolysis Probes (TaqMan): These probes rely on the 5' exonuclease activity of Taq polymerase to cleave the DNA between two dyes. One dye is fluorescent, and the other dye acts as a fluorescence quencher. Cleavage of the DNA probe between these two dyes releases the fluorescent dye from quenching.

Hybridization Probes: These probes show an increase in FRET as product accumulates. One probe is labeled at the 5' end with a fluorescent dye, and, to avoid extension, modified at the 3' end by phosphorylation. The second probe is labeled at the 3' end with a different fluorescent dye. Only after hybridization to the template DNA do the two probes come in close proximity, resulting in FRET between the two fluorophores.

mL: Milliliter (1/1,000 of a liter). A unit of measurement for liquids.

LED: Light emitting diode. Light source for fluorescing the probes in the samples.

PCR: Polymerase Chain Reaction. A key technique in molecular genetics used to analyze and reproduce (amplify) selected short sequences of DNA (or RNA). Previously, amplifying was done in bacteria and took weeks. But now, with PCR done in capillaries, it takes less than 30 min. The method is highly efficient so that untold numbers of copies can be made of DNA.

RNA: Ribonucleic acid. A nucleic acid molecule formed upon a DNA template and similar to DNA but containing ribose rather than deoxyribose. There are several classes of RNA molecules, all of which play crucial roles in protein synthesis and other cell activities.

Screen Test: A mode in the JBAIDS software that allows the user to assay more than one organism from a single sample.

TAMRA: Tetramethyl, 6-carboxyrhodamine. A fluorescent dye commonly used in hydrolysis probes; detected in channel 3 on the instrument.

Transcription: The first step in carrying out genetic instructions in living cells wherein the genetic code is transferred from DNA to molecules of messenger RNA, which subsequently directs protein manufacture.

Translation: the process by which information in messenger RNA directs the sequence of amino acids assembled by a ribosome during protein synthesis.

Taq Polymerase: Enzyme essential for PCR to occur. It “reads” the DNA sequence and facilitates the product extension by assembling each nucleotide.

µL: Microliter (1/1,000,000 of a liter). A unit of measurement for liquids.

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